IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: **BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION**	MD No. 2641 **STIPULATED PROTECTIVE ORDER**

The parties, through their respective counsel, stipulate to the entry of a protective order to govern the dissemination of documents, materials, and other information, including the substance and content thereof, designated by any party as confidential and produced by any party in support of motions, in response to written discovery, or during any formal or informal discovery in this litigation subject to the terms as set forth below.

WHEREAS, the defendants to this action, through their counsel, have requested of the plaintiffs that a protective order preserving the confidentiality of certain documents and information should be entered by the Court.

THEREFORE, IT IS ORDERED as follows:

I. Definitions

1. **Confidential Information**. "Confidential Information" is defined herein as any information that constitutes, reflects, discloses, or contains: (1) a "trade secret" or other confidential research, development, or commercial information" that is suitable for protection under Federal Rule of Civil Procedure 26(c)(1)(G); and (2) information that may be protected from disclosure under a party's constitutional right of privacy such as

confidential and private psychiatric, psychological, medical condition and/or employment information.

2. **Trade Secret**. A party, in designating information "Confidential" because it contains a "Trade Secret", shall designate only information that meets the definition of trade secret contained in 18 U.S.C.A. §1839 (West):

> the term "trade secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if --
>
> (A) the owner thereof has taken reasonable measures to keep such information secret; and
>
> (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

3. **This Action**. "This Action" means IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION, MDL No. 2641, pending in the transferee district, the United States District Court District of Arizona, as per the Transfer Order issued by the United States Judicial Panel on Multidistrict Litigation on August 17, 2015 (Doc. 31) and all cases filed in or transferred to the District of Arizona as a result of the Transfer Order in the above captioned matter.

II. Information Within the Scope of the Protective Order

4. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during This Action, including all copies, excerpts summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any party to This Action or its representatives (the "Supplying Party") to any other party or parties to This Action or their representatives (the "Receiving Party"), whether provided voluntarily, pursuant to formal discovery procedures, or otherwise.

5. The scope of confidentiality protections afforded under this Protective Order does not include any trial exhibits or trial testimony entered into evidence during the case known as *Phillips v. C.R. Bard, Inc., et al.*, No. 3:12-cv-00344-RCJ-WGC (D. Nev. June 1, 2015) (*See*, **Exhibit C**, Order denying Bard's motion to seal trial exhibits and trial transcripts, Doc. No. 328). Notwithstanding the foregoing, this Protective Order does not address or alter whether or not Defendants may argue that non-confidential documents should still be entitled to protection under the work-product doctrine and/or the attorney-client communication privilege.

III. Designating Information As "Confidential" Pursuant to This Protective Order

6. **Documents**. Any Supplying Party producing documents that contain information that meets the definition of Confidential Information as provided in Paragraph 1 and 2 herein, may designate the contents of the documents as "Confidential" prior to or at the time of production by placing the following designation on the documents: "CONFIDENTIAL – Subject to Protective Order". Where a document consists of more than one page, each page of the document shall be designated as such. Any document or information for which it is impracticable or impossible to affix such a legend may be designated by written notice to that effect with a reasonable description of the material in question including a BATES number, where applicable.

7. If a Supplying Party makes documents or information available for inspection, rather than delivering copies to another party, no "Confidential" designation is required in advance of the initial inspection. For the purposes of initial inspection only, the documents shall be considered "CONFIDENTIAL". Upon production of the inspected documents, the Supplying Party shall designate which of the produced or copied documents and materials are or contain Confidential Information pursuant to Paragraph 6 of this Order.

8. **Written Discovery**. If responses to written discovery contain Confidential Information as defined in Paragraph 1 and 2 of this Protective Order, the Responding Party may designate the responsive documents and information, as set forth in

Paragraph 6, with specific indication of the page and line references of the material that is "Confidential" under the terms of this Protective Order.

9. **Depositions**. The parties may designate as Confidential any deposition transcript, or portions thereof, in This Action that meets the definition of Confidential Information provided in Paragraphs 1 and 2 of this Protective Order. Counsel for the designating party shall advise the court reporter and the parties on the record during the deposition or by letter no later than thirty (30) calendar days after the court reporter provides the parties with the final deposition transcript. If any portion or all of a deposition transcript is designated as Confidential Information, the court reporter shall label the cover page of the original and one copy of the transcript to state that Confidential Information is contained therein, and shall label as "Confidential" each page of the transcript and/or exhibits to the deposition transcript that constitute "Confidential Information". Confidential designations of transcripts or portions thereof, apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript or portion thereof prior to the expiration of the 30-day period as "DO NOT DISCLOSE – SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Deposition transcripts or portions thereof will be treated as Confidential Information until expiration of the 30-day period. If any party does not designate the transcript as "Confidential" either at the time of the deposition or within the 30-day period defined above, no portion of the entire transcript will be deemed "Confidential" and the "DO NOT DISCLOSE-SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed. The 30-day period may not be extended without mutual agreement of the parties.

10. **Confidential Information Produced By Third Parties**. A party in This Action may designate as Confidential any document, information, or testimony produced or supplied by any person or entity not a party to This Action, that constitutes or meets the definition of Confidential Information as defined in Paragraphs 1 and 2 of this Protective Order. The party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any party receiving information from a

third party shall treat such information as Confidential Information during this thirty (30) day period while all parties have an opportunity to review the information and to determine whether it should be designated as confidential. Any party designating third party information as Confidential Information shall have the same rights, duties, and obligations, as a Supplying Party under this Protective Order.

11. **Publicly Available Information.** The confidentiality restrictions and confidentiality obligations set forth herein shall not apply to information that is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party, generally available to the public through publication or otherwise. This includes information published during public hearings and trials, if the Supplying Party does not move to seal or appeal any order denying such motion to seal within the time permitted under the applicable rules. Notwithstanding the foregoing, this Protective Order does not address or alter whether or not Defendants may argue that non-confidential documents should still be entitled to protection under the work-product doctrine and/or the attorney-client communication privilege.

IV. Limitations on Use of Confidential Information

12. All Confidential Information shall be used for the purpose of this lawsuit only, and except as permitted by this Order, the parties and their respective attorneys, as well as experts or consultants, shall not give, show, or otherwise divulge or disclose the Confidential Information, or any copies, prints, negatives or summaries thereof to any person or entity. Notwithstanding the foregoing provisions of this paragraph, nothing in this Order shall prevent the use of any of the documents or electronically stored information ("ESI") produced pursuant to this Protective Order in other actions brought by the plaintiff's counsel, so long as a comparable protective order is entered in those other actions.

13. Confidential Information pursuant to this Protective Order shall be treated by the parties, their counsel, and any other signatory to this Protective Order as being confidential and private. Any copy of Confidential Information shall have the same status

as the original. The disclosure and use of Confidential Information shall be confined to the permissible disclosures and uses set forth in this Protective Order, and no one shall disclose or use Confidential Information in a manner inconsistent with the terms and the intent of this Protective Order.

14. Confidential Information may be disclosed only to the following persons and shall be used solely for the litigation of This Action and may not be disclosed to anyone not authorized under this paragraph:

a. Parties, their representatives, in-house counsel and regular employees who are actively engaged in, or actively overseeing This Action;

b. Counsel of record, their associated attorneys, and support staff, including paralegal and secretarial personnel who are working on This Action;

c. Experts and consultants (including their employees/contractors) who are consulted or retained by a party to assist in the litigation of This Action;

d. Third-party contractors and their employees who are consulted or retained by one or more parties to provide litigation-support or copy services in connection with the litigation of This Action

e. Witnesses or prospective witnesses in This Action;

f. Court reporters, videographers, and other persons involved in recording deposition testimony in This Action;

g. The Court and its personnel, including any mediators and/or special masters appointed by the Court, or if an appeal, the court with appellate jurisdiction; and

h. Jurors in This Action

15. Prior to the disclosure of any Confidential Information to any person identified in Paragraph 14 above (except the Court and its personnel and jurors in This Action), the disclosing party will provide each potential recipient of Confidential

Information with a copy of this Protective Order, which said recipient shall read. Upon reading this Protective Order, such person shall sign an Acknowledgment, annexed to this Protective Order as **Exhibit A**, acknowledging that he or she has read this Protective Order and shall abide by its terms. Notwithstanding the foregoing provision, Confidential Information may be disclosed to a witness who will not sign an Acknowledgment in a deposition at which the party who has designated the Confidential Information is represented or has been given notice that Confidential Information produced by the party may be used. These Acknowledgments are strictly confidential and shall be maintained by counsel for each party and only with good cause shown and separate court order will the Acknowledgments be disclosed to the opposing side. Persons who come into contact with Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgments but must comply with the terms of this Protective Order.

16. All persons receiving or given access to Confidential Information in accordance with the terms of this Order consent to the continuing jurisdiction of this Court for the purposes of enforcing this Order and remedying any violations thereof.

17. Confidential Information shall not be placed or deposited in any sort of data bank that is made available for indiscriminate or general circulation to lawyers, litigants, consultants, expert witnesses or any other persons not working on This Action and not signatories to this Protective Order. This paragraph and the other provisions of this Order shall not apply to materials which, if challenged by any party, the Court rules are not entitled to protection. This paragraph does not limit or restrict in any way the manner in which a party may store and make Confidential Information available to the attorneys, support staff, experts, and any other persons or entities working on This Action, provided the general terms of this Order are followed.

18. The parties and their counsel as well as their technical consultants and experts shall also not sell, offer, advertise, publicize nor provide under any condition any Confidential Information produced by any other party to any competitor of any defendant

or to any employee or any competitor (irrespective of whether they are retained as an expert by a party in This Action).

19. In the event that either of the parties is served by a non-party with a subpoena for Confidential Information that was originally provided and claimed as Confidential by another party, the Receiving Party will give notice to the Supplying Party, where reasonably possible, no less than ten (10) business days prior to disclosure by providing a copy of the subpoena, to allow a reasonable opportunity for the Supplying Party to object to such production before any production takes place.

20. If a Receiving Party learns of any unauthorized disclosure of Confidential Information, it shall take reasonable efforts to immediately (a) inform the Supplying Party in writing of such disclosure, including to whom the material was disclosed; (b) make a reasonable effort to retrieve all copies of the Confidential Information only to the extent the Receiving Party has control over the unauthorized disclosed documents; (c) and to the extent the Receiving party has control over the person or persons to whom unauthorized disclosures were made, inform the persons of the terms of this Protective Order.

V. Changes In and Objections to Designation of Information

21. **Inadvertent Disclosure of Confidential Information**. If a Supplying Party through inadvertence produces any documents containing Confidential Information without designating the documents as such in accordance with Paragraph 6 of this Protective Order, such inadvertence does not waive any claim for confidentiality that the Supplying Party may possess so long as the Supplying Party notifies the Receiving Party of the Confidential Information designation in writing within twenty (20) days of the date that the Supplying Party became aware or reasonably should have become aware of the failure to designate the information as Confidential Information. If a Supplying Party fails to designate information as Confidential Information within this twenty (20) day period, the Supplying Party waives its right to designate the documents as Confidential Information. The Supplying Party shall also supply the Receiving Party with a new copy of the documents designated in accordance with Paragraph 6 of this Protective Order,

which shall be substituted for the undesignated documents. Upon receipt of the substitute documents, the Supplying Party shall promptly return or destroy the improperly-designated document(s). Upon receipt of the Supplying Party's notice of the inadvertent disclosure, the Receiving Party shall, within a reasonable time, not exceed twenty (20) days, (a) treat such material in accordance with this Order; (b) take reasonable steps to notify any person to whom the Receiving Party disclosed such information of the new confidential designation; (c) take reasonable steps to procure the return of all copies of such material from any such persons who are not entitled to receipt of Confidential Information under the terms of this Protective Order ; (d) request in writing that such person procure the return of such information from any person to whom such person may have disclosed the information.

Notwithstanding the foregoing provisions of this section, the Supplying Party shall be deemed to have waived any claim of confidentiality with respect to the information inadvertently not claimed as confidential to which the Supplying Party fails to claim as Confidential Information, prior to sixty (60) days from the close of discovery.

22. **Challenges to Designation of Confidential Information**. A Receiving Party may challenge a Supplying Party's designation or redesignation by notifying the Supplying Party in writing that the confidentiality designation does not meet the definition of "Confidential Information". The designation by any party of Confidential Information raises no presumption that the information or documents are entitled under the law to protection. If any party contends, in writing, that any document, material, ESI, or other thing has been erroneously designated as Confidential Information, the party who designated the information as Confidential Information shall initiate a meet and confer within ten (10) days with the opposing party and the parties shall make a good faith effort to resolve issues relating to such designations. After the meet and confer, the party who designated the information as Confidential Information shall file a motion with the Court within thirty (30) days of receiving such written notification establishing that the information is entitled to protection as Confidential Information under the law. If the

designating party fails to timely file such a motion within the allotted thirty (30) day period, the document, ESI, material, or other thing, which is designated as Confidential Information, shall forthwith be produced and be deemed not to be Confidential Information. Any information or thing being challenged as inappropriately designated as Confidential Information shall nonetheless be treated as Confidential Information unless and until either (a) the designating party gives written permission to do otherwise, (b) the designating party fails to file a motion establishing that the challenged material is subject to protection as Confidential Information under the law within the thirty (30) day time period, or (c) the Court rules that the document, material, ESI, or other thing shall not be treated as confidential. Should the Court rule that any item designated as Confidential Information is not entitled to protection under the law, the designating party shall, within fourteen (14) days after all appeals are exhausted, provide the party challenging the confidential designation with copies of each item free of any language indicating that the item is subject to a Protective Order.

23. **Nothing in this Order shall be deemed to shift the burden of proof to the party challenging the confidential designation with regard to whether the materials produced pursuant to his Order are entitled to protection under the law as Confidential Information.**

VI. Filing Under Seal

24. **Where a Party Files Documents and Contends the Documents Should be Kept Sealed.** Where a party intends to file documents that contain Confidential Information with the Court, said party must file a motion for an order sealing the documents consistent with applicable law and comply with the provisions of Local Rule of Civil Procedure 5.6. A copy of the motion must be served on all parties that have appeared in the case.

25. **Where a Party Files Documents Claimed as Confidential by Another Party**. A party that files or intends to file with the Court Confidential Information

produced by another party but does not intend to request to have the records sealed, must do the following:

a. Make arrangements consistent with Local Rule of Civil Procedure 5.6 to lodge the documents under seal in accordance with local rules.

b. File redacted copies of the documents (if appropriate) so that they do not disclose the contents of the records that are subject to the confidentiality agreement or protective order;

c. Serve a copy of the motion on all parties that have appeared in the case; and

d. Give written notice to the party that produced the documents that the documents will be placed in the public court file unless the party files a timely motion to seal records.

If the party that produced the Confidential Information and was served with the above-mentioned notice fails to file a motion to seal the records within fifteen (15) days of receipt of the notice referenced in subsection 25(d) or to obtain a court order extending the time to file such motion, the clerk must promptly remove all the documents filed under seal pursuant to this provision from the envelope or container where they are located and place them in the public file. If the party files a motion or an application to seal within fifteen (15) days of receipt of the notice referenced in subsection 25(d) days or such later time as the Court has ordered, these documents are to remain conditionally under seal until the Court rules on the motion or application and thereafter are to be filed as ordered by the Court.

This section shall not apply with respect to documents admitted into evidence as exhibits at the trial of this matter. The Supplying Party reserves the right, however, to petition the Court for protection with respect to such documents admitted into evidence as exhibits at trial.

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VII. Miscellaneous Provisions

26. **Amending or Modifying Protective Order.** By written agreement of the parties, or upon motion and order of the Court, the terms of this Protective Order may be amended or modified. This Protective Order shall continue in force until amended or modified by consent or agreement of the parties or by order of the Court, and shall survive any final judgment or settlement in This Action, including but not limited to any final adjudication of any appeals petitions for extraordinary writs, unless otherwise vacated or modified by the Court. The Court shall have continuing jurisdiction over the terms and provisions of this Protective Order.

27. **After Final Adjudication**. Upon written demand by the Supplying Party made within thirty (30) days after final adjudication of This Action, including but not limited to, any final adjudication of any appeals and petitions for extraordinary writs, the Receiving Party shall assemble and return all Confidential Information to the Supplying Party or, alternatively, shall destroy all such material at the Supplying Party's expense. The Receiving Party shall verify the complete destruction or return to the Supplying Party all such Confidential Information by executing and mailing to counsel for the Supplying Party an Acknowledgment in the form attached hereto as **Exhibit B**. A copy of each such executed Acknowledgment shall be maintained by counsel for the Receiving Party and counsel for the Supplying Party. Notwithstanding the foregoing provisions of this paragraph, the Receiving Party may maintain its privileged communications, work product, Acknowledgments pursuant to the Protective Order, materials required to be retained pursuant to applicable law, and all court-filed documents even though they contain Confidential Information, but such materials shall remain subject to the terms of this Protective Order. This provision may not be invoked while the plaintiff's attorneys of record have active pending cases relating to IVC Filters manufactured by C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc.

28. The terms of this Protective Order do not preclude, limit, restrict, or otherwise apply to the use of Confidential Information at trial. The use of Confidential

Information during trial will be addressed in a later agreement between the parties, or, if they cannot reach an agreement, by further order of the Court.

29. Nothing in this Order shall be deemed a waiver of any parties' right to oppose any motion by any other party for a protective order or to oppose any objection to the disclosure of any information or documents on any legal grounds, including, but not limited to, the grounds that the party seeking the protective order has neither timely nor adequately objected to disclosure of such documents and information or moved for a protective order.

30. This Protective Order does not relieve any party of its obligations to respond to otherwise proper discovery in This Action. Nothing contained in this Order, or any action taken pursuant to it shall waive or impair any party's right to assert claims of privilege or work product protection, or the right of any party to object to the relevancy of admissibility of documents or information sought or produced into assert objections to requested discovery on grounds other than Confidential Information. This Protective Order also shall not affect or create any presumption with respect to the right of any party from seeking or obtaining additional protection with respect to any documents, materials, or information where allowed by law.

31. **Inadvertent Production.** Pursuant to Rule 502 of the Federal Rules of Evidence, inadvertent production of documents or electronically-stored information (hereinafter collectively "Inadvertently-Produced Documents") subject to work product immunity, the attorney-client privilege, or other legal privilege protecting information from discovery shall not constitute a waiver of immunity or privilege in the pending case or in any other federal or state proceeding. In the event that a party inadvertently produces documents or ESI subject to a claim of privilege, the Supplying Party shall, within 15 days of the discovery of the inadvertent disclosure, notify the other party in writing of the inadvertent disclosure. The Supplying Party may, in the notice, request a "clawback" of the inadvertently disclosed material. Upon receiving notice of the inadvertent production, the parties agree to follow the procedures provided by Federal Rules of Civil

Procedure 26 (b)(5)(B) respect to the clawback of the Inadvertently Produced Documents. All notes or other work product of the Receiving Party, reflecting the contents of such materials, shall be destroyed and not used.

If the party receiving such Inadvertently-Produced Documents moves the Court to dispute the claim of privilege or immunity, the party shall not assert the fact or circumstances of the inadvertent production to challenge whether the material is, in fact, privileged. Likewise, as part of any such motion, the Receiving Party shall not challenge the "reasonable steps", as described in Rule 502(b) of the Federal Rules of Evidence, taken or not taken by the Supplying Party.

Pursuant to Rule 502(d) of the Federal Rules of Evidence, there is no waiver of privilege or work product immunity in this matter or any other matter in any other jurisdiction for any document or ESI returned or destroyed under this subsection, or for the subject matter of any such document or ESI, whether the privileged document or ESI was inadvertently produced following review or as part of a "Quick Peek" production. In the event that either party receives information produced in discovery from the other party that reasonably appears to be Inadvertently-Produced Documents, the Receiving Party shall promptly notify the Supplying Party in writing of the apparent inadvertent production.

32. Each party shall retain all rights and remedies available to it under the law for the enforcement of this Protective Order against anyone who violates it.

33. Nothing in this Protective Order shall be construed to prevent this Court from disclosing any facts the Court relies upon in making any findings or issuing any ruling, order, judgment, or decree.

34. Within thirty (30) days of any information that has been claimed as Confidential Information being de-designated or made publically available, the Supplying Party shall provide notice of the Confidential Information that has been de-designated and/or made publicly available. Such notice shall be made by identifying bates numbers or by other means such as identifying categories of information where the identification of

bates numbers are not possible or not feasible. Publically available includes documents that have been filed with any court or entered as an exhibit during trial not under seal, provided, however that the Supplying Party is not required to provide notice of de-designation with regard to such documents until any motion or request to seal those documents is denied. This paragraph only applies to the extent that the Supplying Party knew or should have known that the information claimed as Confidential Information was de-designated or made publically available.

Dated this 9th day of November, 2015.

David G. Campbell
United States District Judge

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MD-15-02641-PHX-DGC **AGREEMENT TO MAINTAIN CONFIDENTIALITY**

I, _____ (Name), have been given and have read a copy of the Protective Order, dated _____, 2015 in the case of MDL No. 2641, pending in the United States District Court District of Arizona. I understand and will strictly adhere to the contents of said Order. I understand that produced material disclosed to me is subject to the Order of this Court and that I am prohibited from copying, disclosing or otherwise using such material except as provided by said court Order. I understand that my unauthorized disclosure of any "Confidential Information" may constitute contempt of court and I agree to be personally subject to the jurisdiction of this Court for the purpose of enforcing my obligations under this Agreement, the Order, and any contempt proceeding that may be instituted for my violation of the terms of this Acknowledgment and the Protective Order. I also understand that my signature on this "Agreement to Maintain Confidentiality", indicating my agreement to be bound by the terms of this Protective Order, is required before I may be allowed to receive and review any produced document and materials that are designated as "Confidential Information" .

Date: _____ Print Signature:_____

Signature:_____

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MD-15-02641-PHX-DGC **ACKNOWLEDGEMENT OF DESTRUCTION OR RETURN OF CONFIDENTIAL INFORMATION**

I, _____ (Name), am over the age of 18 years and am a resident of _____ County, _____. I make this Declaration based upon my personal knowledge, and I am competent to testify to the matters stated herein.

I have requested and received from _____ all of the "Confidential Information" contained in materials, transcripts, and other things within the scope of this Protective Order and produced in this case MDL No. 2641, pending in the United States District Court District of Arizona.

I have either destroyed or have attached hereto all of the "Confidential Information" contained in the materials, transcripts, and other things within the scope of this Protective Order including those materials which were returned to me by the experts and consultants mentioned above in accordance with the preceding paragraph, and as described in the Protective Order related to this matter. Notwithstanding the foregoing provisions of this paragraph, the Receiving Party may maintain its privileged communications, work product, Acknowledgments pursuant to the Protective Order, materials required to be retained pursuant to the applicable law, and all court-filed documents even though they contain "Confidential Information," but such materials shall remain subject to the terms of this Protective Order.

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I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____ Print Signature:_____

Signature:_____

EXHIBIT C

[PHILLIPS ORDER ON MOTION TO SEAL, 6.1.15]

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

KEVIN PHILLIPS,

Plaintiff,

vs.

C.R. BARD, INC. et al.,

Defendants.

3:12-cv-00344-RCJ-WGC

ORDER

This case arises out of an allegedly defective medical device. The parties settled during trial. Defendants have asked the Court to seal certain trail exhibits and portions of the trial transcript.

A court may "make any order which justice requires to protect the party or person from annoyance, embarrassment, oppression or undue burden or expense" upon motion by a party or a person from whom discovery is sought. Fed. R. Civ. Pro. 26(c). "The mere fact that the production of records may lead to a litigant's embarrassment, incrimination, or exposure to further litigation will not, without more, compel the court to seal its records. *Kamakana v. City & Cnty. of Honolulu*, 447 F.3d 1172, 1179 (9th Cir.2006). There is a strong presumption towards public access to judicial records. *See id.* at 1178. Under *Kamakana*, judicial records are

separated into two groups, each with its own standard to be met if litigants wish to seal them. First, judicial records attached to dispositive motions must meet the "compelling reasons" standard in order for those documents to be sealed. *Id.* at 1180. Those compelling reasons must outweigh the competing interests of the public in gaining access to the judicial records and to understand the judicial process. *Id.* at 1178–79. Second, judicial records attached to nondispositive motions must meet the lesser "good cause" standard to be sealed. *Id.* A motion to seal transcripts and evidence adduced at trial must satisfy the "compelling reasons" test, because a trial is a dispositive proceeding. *In re Elec. Arts, Inc.*, 298 Fed. App'x 568, 569 (9th Cir. 2008). The Court of Appeals has rejected requests to seal documents under the "compelling reasons" standard where the movant makes nothing more than "conclusory statements about the content of the documents—that they are confidential and that, in general," their disclosure would harm the movant. *Id.* at 1182.

Defendants argue that three categories of material should be sealed: (1) product design and testing, including confidential communications between Defendants and the FDA; (2) sales and marketing information; and (3) Defendant's internal quality control procedures, complaint and adverse event responses, reporting and handling, device tracking procedures, and corrective action procedures. The Court finds that these categories of information do not satisfy the compelling reasons test. The only harm that could come to Defendants form the release of this information is the precipitation of further lawsuits against it. Preventing lawsuits due to the release of inculpating information is not a compelling reason to seal otherwise public legal proceedings. Indeed, the exposure of facts relevant to the material claims in a lawsuit is the

purpose of a trial, and these facts should remain public unless the harm likely to result from their release is unrelated to the nature of the claims. The information does not directly implicate trade secrets.

Even if the test could be satisfied, Plaintiff correctly notes that Defendants have waived the issue because Defendants made no motion to seal the exhibits or testimony at the public trial. *See, e.g.*, *Gambale v. Deutsche Bank AG*, 377 F.3d 133, 144 & n.11 (2nd Cir. 2004); *Littlejohn v. BIC Corp.*, 851 F.2d 673, 680 (3d Cir. 1988); *Nat'l Polymer Prods. v. Borg–Warner Corp.*, 641 F.2d 418, 421 (6th Cir. 1981); *Level 3 Commc'ns, LLC v. Limelight Networks, Inc.*, 611 F. Supp. 2d 572, 588 (E. D. Va. 2009) ("The First Amendment public right of access to these exhibits sprang into existence upon their being offered into evidence for the jury's consideration at trial, and since no request was made to seal them prior to or at that time, Savvis waived any future right to assert any competing interest to be weighed by the Court and, thus, any objection to the public availability of the exhibits in the Court's files.").

CONCLUSION

IT IS HEREBY ORDERED that the Motion to Seal (ECF No. 317) is DENIED.

IT IS FURTHER ORDERED that the Motion (ECF No. 326) is DENIED without prejudice, as it has been incompletely filed.

IT IS SO ORDERED.

Dated this 1st day of June, 2015.

ROBERT C. JONES
United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves more than 3,000 personal injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters. Each Plaintiff received a Bard IVC filter implant and claims that the filter is defective and has caused Plaintiff to suffer serious injury or death. Plaintiffs assert various state law claims and seek both compensatory and punitive damages.

In this motion, Bard seeks summary judgment on the ground that Plaintiffs' state claims are expressly preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360 et seq., and impliedly preempted by the MDA under the Supreme Court's conflict preemption principles. Doc. 5396. The motion is fully briefed, and the Court heard oral arguments on November 17, 2017. The Court will deny Bard's motion.

I. Background.

The Court will begin by describing IVC filters and their uses, the history of the MDA, the relevant regulatory process, and the claims asserted by Plaintiffs.

A. IVC Filters.

The IVC is a large vein that carries de-oxygenated blood from the lower body to the heart. IVC filters are small metal devices implanted in the upper portion of the IVC to stop blood clots from travelling to the heart and lungs. Blood clots often develop in the legs from a condition called deep vein thrombosis or "DVT." Once blood clots reach the lungs, they are deemed pulmonary emboli or "PE." Pulmonary emboli and other thromboembolic events, such as strokes, can cause serious injury or death.

People at risk for DVT and PE may be prescribed blood thinners such as Heparin or Warfarin to help prevent blood clots. But these medications do not prevent blood clotting for certain people at high risk for DVT or PE, and blood thinners may not be an option for bariatric and trauma patients who could experience thromboembolic events during surgery. In those situations, physicians may recommend implanting an IVC filter to catch any blood clots before they reach a vital organ.

IVC filters originally were designed to be implanted permanently. Because some patients need only temporary filters, however, medical device manufacturers such as Bard developed retrievable filters. Bard first obtained Food and Drug Administration ("FDA") clearance to market a retrievable IVC filter in 2003. Seven different versions of Bard filters are at issue in this MDL – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali. They are spider-shaped devices with multiple struts fanning out from a cone-shaped head. The struts consist of legs with hooks that attach to the IVC wall, and shorter curved arms that serve to catch or break up blood clots. Each of these filters is a variation of its predecessor. The last-generation Denali filter received FDA clearance in May 2013. The filters are designed to be retrievable using Bard's Recovery Cone Removal System.

B. History of the MDA.

Throughout our history, states have exercised police powers to protect the health and safety of their residents. The federal government first entered this field more than a century ago with passage of the Food and Drug Act of 1906, 34 Stat. 768, which

prohibited the manufacture of adulterated or misbranded food and drugs. Congress broadened the coverage of the statute to include misbranded or adulterated cosmetics and medical devices in the Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq.

The FDCA required premarket approval for new drugs, but not new medical devices. As technology advanced and reliance on medical devices grew, policymakers and the public became concerned about the increasing number of injuries resulting from device failures. Notable in this regard were injuries women suffered from the Dalkon Shield contraceptive device in the 1960s and early 1970s. Other devices, including catheters, artificial heart valves, and pacemakers, also created possible health risks. Several states responded with regulatory measures, such as California's 1970 law requiring premarket approval of medical devices. 1970 Cal. Stats. ch. 1573, §§ 26670-26693.

In 1976, Congress passed the MDA "to provide for the safety and effectiveness of medical device[s] intended for human use[.]" Pub. L. No. 94-295, 90 Stat. 539 (1976). The MDA extends coverage of the FDCA to medical devices through federal oversight measures implemented by the FDA. It also curtails state regulation of medical devices through a provision that preempts state requirements that differ from or add to federal requirements. 21 U.S.C. § 360k.

C. FDA Regulatory Process.

The MDA gives the FDA broad powers to classify and regulate medical devices. The FDA assigns medical devices to Class I, Class II, or Class III based on their risk levels. Class I devices, which include products such as bandages and tongue depressors, are low-risk and subject to oversight only through "general controls" such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A). Class II devices pose moderate health risks. The original MDA definition of a Class II device identified performance standards as the means by which the FDA could reasonably ensure safety and effectiveness. The Safe Medical Devices Act of 1990 ("SMDA"), Pub. L. 101-629, added various "special

controls" for this purpose. The special controls may include FDA guidance documents, premarket data requirements, performance standards, postmarket surveillance measures, and patient registries. 21 U.S.C. § 360c(a)(1)(B). Class III includes devices used to support human life, such as pacemakers and hearts valves, and devices that pose a high risk of injury. 21 U.S.C. § 360c(a)(1)(C). They receive the highest level of regulatory control.[1] IVC filters originally were designated as Class III devices, but were moved to Class II, along with many other pre-MDA devices, in 2000. *See* 65 Fed. Reg. 17138, 17144 (Mar. 31, 2000); 21 C.F.R. § 870.3375.

The FDA applies different levels of scrutiny to medical devices before approving or clearing them for market, and the level of scrutiny can affect whether state laws are preempted. The most rigorous level of scrutiny is known as "premarket approval," often referred to as the "PMA process." 21 U.S.C. § 360e(a). To comply, a manufacturer must file an application that provides a wide range of detailed information to the FDA in order to demonstrate that the device is safe and effective. *See* 21 U.S.C. § 360e(c). If the FDA finds the device safe and effective, it approves the device for marketing.[2]

Others medical devices can be cleared for market through a less rigorous process known as section "510(k)" review after the original statutory provision describing the review. A manufacture can satisfy this level of review, and be exempt from the PMA process, by providing premarket notice to the FDA that its device is "substantially equivalent" to a predicate device already on the market.[3] § 360c(f)(1)(A). This 510(k)

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[1] *See generally FDA Medical Devices, Regulatory Controls* (last updated June 26, 2014), *available at* https://www.fda.gov/ MedicalDevices/DeviceRegulationandGuidance /Overview/GeneralandSpecialControls/default.htm (last visited Nov. 17, 2017).

[2] *See generally FDA Medical Devices, Device Advice: Comprehensive Regulatory Assistance* (last updated Sept. 29, 2017), *available at* https://www.fda.gov/Medical Devices/DeviceRegulationandGuidance/ (last visited Nov. 17, 2017).

[3] A "predicate device" is one that (1) was legally marketed before passage of the MDA and no PMA process was required, (2) has been reclassified from Class III to Class II or I, or (3) has been found to be a substantially equivalent device through 510(k) review. 21 C.F.R § 807.92(a)(3). A device is "substantially equivalent" to a predicate device where it has the same intended use and (1) has "the same technological characteristics as the predicate device," or (2) any technological differences "do not raise different questions of safety and effectiveness than the predicate device."

review is more streamlined than the PMA process and focuses primarily on equivalence rather than safety and effectiveness. If a 510(k) notice results in an FDA finding of substantial equivalence, the device is cleared for marketing.

The FDA maintains a bright line between devices "approved" through the PMA process and devices "cleared" through 510(k) review. PMA approval results in a finding of safety and effectiveness, while 510(k) clearance results only in a finding of substantial equivalence. FDA regulations require manufacturers to maintain this distinction:

> Submission of a [510(k) notice] in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution . . . does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with [510(k) notification] is misleading and constitutes misbranding.

21 C.F.R § 807.97.

The Bard IVC filters at issue in this case, like most medical devices on the market today, received FDA clearance through 510(k) review. Each Bard filter was deemed to be substantially equivalent to a predicate filter already on the market. No Bard filter has received FDA approval through the PMA process.

D. Plaintiffs' Claims.

Plaintiffs allege that Bard IVC filters are defective. Plaintiffs contend that the filters tilt, perforate the IVC, and fracture and migrate to neighboring organs such as the heart and lungs. Plaintiffs claim that Bard filters are more dangerous than other kinds of IVC filters, and that Bard concealed adverse information and otherwise failed to warn the medical community and the public about the risks posed by its filters. Bard vigorously disputes Plaintiffs' allegations of high risk levels, contending that overall complication rates associated with Bard filters are low and comparable to those of other IVC filters.

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§ 360c(i)(1)(A); *see* 21 C.F.R. § 807.100(b) (describing criteria the FDA uses in its substantial equivalence review).

Plaintiffs' master complaint asserts 17 causes of action under various state laws: strict product liability claims for manufacturing, information, and design defects (Counts I-III); negligence claims for design, manufacturing, failure to recall or retrofit, failure to warn, misrepresentation, and per se negligence (Counts IV-IX); breach of warranties (Counts X-XI); fraudulent misrepresentation and concealment (Counts XII-XIII); consumer fraud and unfair trade practices (Count XIV); loss of consortium (Count XV); wrongful death (Count XVI); and survival claims (Count XVII). Doc. 303-1.[4]

Bard seeks summary judgment on each cause of action, arguing that the MDA preempts them all. Doc. 5396 at 14-34.[5] For reasons explained below, the Court finds that Bard has not met its burden of establishing preemption and therefore will deny summary judgment.

II. Summary Judgment Standard.

A party seeking summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes over facts that might affect the outcome of the suit will preclude summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence of the nonmoving party is to be believed, and all reasonable inferences are to be

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[4] The master complaint is the operative pleading for most of the cases in this MDL. It was created for the sake of convenience and serves as a long-form complaint giving notice, pursuant to Rule 8, of the allegations that Plaintiffs assert in this case. Plaintiff -specific allegations are contained in individual short-form complaints or certain complaints served on Bard before the filing of the master complaint. *See* Doc. 249. Plaintiffs also provide Bard with fact sheets that describe their individual conditions and claims. *See* Doc. 365.

[5] Page citations are to numbers placed at the top of each page by the Court's electronic filing system rather than the document's original page numbers.

drawn in that party's favor, because the weighing of evidence and drawing of inferences are jury functions. *Id.* at 255.

III. Basic Preemption Principles.

"When a transferee court receives a case from the MDL Panel, the transferee court applies the law of the circuit in which it is located to issues of federal law." *In re Gen. Am. Life Ins. Co. Sales Practices Litig.*, 391 F.3d 907, 911 (8th Cir. 2004). In this case, that would be the law of the Ninth Circuit. Thus, in performing its federal preemption analysis, the Court will look primarily to Supreme Court and Ninth Circuit cases.

"The Supremacy Clause provides a clear rule that federal law 'shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, anything in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting U.S. Const. art. VI, cl. 2). Under this clause, "Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372, (2000).

"'[T]he purpose of Congress is the ultimate touchstone'" in determining whether Congress has preempted a state law. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)). Federal preemption may be either express or implied. *Attay v. Cty. of Maui*, 842 F.3d 688, 699 (9th Cir. 2016). Where there is no express congressional command, a state law is impliedly preempted if "it actually conflicts with federal law[.]" *Id.* (citing *Cipollone*, 505 U.S. at 516). Conflict preemption occurs "where compliance with both federal and state regulations is a physical impossibility[.]" *Arizona*, 567 U.S. at 399 (internal citations and quotation marks omitted).

"Where the intent of a statutory provision that speaks expressly to the question of preemption is at issue, '[courts] do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Attay*, 842 F.3d at 699 (quoting *Puerto Rico v. Franklin Cal. Tax-Free Trust*, —— U.S. ——, 136 S. Ct. 1938, 1946 (2016)). Where

there is no express preemption and a federal statute regulates in an area "traditionally occupied by states, such as health, safety, and land use, a 'presumption against preemption' adheres." *Gobeille v. Liberty Mut. Ins. Co.*, — U.S. —–, 136 S. Ct 936, 946 (2016) (quoting *Wyeth v. Levine*, 555 U.S. 555, 565 n.3 (2009)).

The Court first will discuss express preemption under § 360k of the MDA, and then turn to implied preemption.

IV. Express Preemption.

Section 360k of the MDA includes this express preemption clause:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The Supreme Court has held that this clause applies when (1) the federal government has established "requirements" applicable to the device in question, and (2) state law claims are based on state requirements that are different from, or in addition to, the federal requirements, and that relate to safety and effectiveness. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008). Consistent with this guidance, the Court first will determine whether the FDA's 510(k) review established federal "requirements" for the Bard IVC filters, and then whether Plaintiffs' state law claims would impose "requirements" different from, or in addition to, any federal requirements.

A. Federal Requirements.

1. Supreme Court Precedent.

The Supreme Court has interpreted § 360k in two cases, *Riegel* and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).[6] *Lohr* involved a pacemaker that was cleared by the

[6] The Supreme Court addressed implied preemption under the MDA in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), but declined to express a view on whether the state claims were expressly preempted under § 360k. *Id.* at 348 n.2.

FDA in 1982 through 510(k) review. The plaintiff, who suffered injuries when her pacemaker failed, brought state common law claims for negligence and strict liability against the manufacturer, Medtronic. The majority opinion in *Lohr* held that § 360k does not preempt state law claims directed at medical devices cleared through the 510(k) process because the substantial equivalence review of that process places no federal requirements on a device. 518 U.S. at 492-94; *see Riegel*, 552 U.S. at 322-23.

Central to the holding in *Lohr* was the Supreme Court's finding that "[t]he § 510(k) notification process is by no means comparable to the PMA process[.]" 518 U.S. at 478-79. *Lohr* noted that the PMA process is a "rigorous" examination of the product in question that takes an average of 1,200 hours to complete, while "the 510(k) review is completed in an average of only 20 hours." *Id.* at 477-79. *Lohr* noted that the "510(k) process is focused on *equivalence*, not safety[.]" *Id.* at 493 (emphasis in original; citation and quotation marks omitted). *Lohr* concluded that the FDA's 510(k) review "did not 'require' Medtronics' pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process." *Id.* at 493-94.

Riegel involved a cardiovascular catheter approved by the FDA through the PMA process. *Riegel* did not disagree with *Lohr*'s conclusion that 510(k) review imposes no federal requirements on manufacturers, but held that the more rigorous PMA process does impose such requirements. 552 U.S. at 322. *Riegel* disagreed with *Lohr*'s view of state law claims and held that such claims can impose requirements within the meaning of § 360k. *Id.* at 322-24. Because the common law tort claims asserted in *Riegel* would impose requirements different from federal requirements established through the PMA process, *Riegel* found the plaintiffs' state law tort claims preempted by § 360k. *Id.* at 323-25.

Riegel was decided nearly 20 years after passage of the SMDA and the start of FDA's use of "special controls" during 510(k) review, and yet the Supreme Court still

found that 510(k) review was not close to the PMA process. *Riegel* described the PMA process in detail and held that it imposes federal "requirements" within the meaning of § 360k. In doing so, *Riegel* distinguished 510(k) review:

> Premarket approval, in contrast [to 510(k) clearance], imposes "requirements" under the MDA as we interpreted it in *Lohr*. Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—it *is* federal safety review. Thus, the attributes that *Lohr* found lacking in 510(k) review are present here.

552 U.S. at 322-23 (emphasis in original).

Riegel explicitly addressed, and did not disagree with, *Lohr*'s finding that 510(k) review imposes no device-specific requirements on manufacturers:

> Even though substantial-equivalence review under 510(k) is device specific, *Lohr* also rejected the manufacturer's contention that 510(k) approval imposed device-specific "requirements." We regarded the fact that products entering the market through 510(k) may be marketed only so long as they remain substantial equivalents of the relevant 1976 devices as a qualification for an exemption rather than a requirement.

552 U.S. at 322.

The Ninth Circuit likewise has recognized significant differences between 510(k) review and the PMA process. In *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013), the circuit court found a state law fraud claim preempted by the MDA because the device at issue, "[l]ike the device in *Riegel*, . . . was subject to device-specific requirements under the PMA [process]." *Id.* at 1118. *Perez* contrasted the 510(k) review in *Lohr*, which imposes no "requirements," with the more rigorous PMA process:

> None of the federal laws or regulations at issue [in *Lohr*] imposed device-specific requirements. In contrast, the Court in *Riegel* held that § 360k preempted common-law claims challenging the safety and effectiveness of a medical device that had received premarket approval from the FDA. Unlike the federal laws and regulations at issue in *Lohr*, premarket approval imposes device-specific requirements.

711 F.3d at 1118; *see also Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en banc) (noting that the Court in *Riegel* "was careful to state that . . . *Lohr* remained good law").

Many cases interpret *Riegel* and *Lohr* to mean that PMA approval preempts different or additional requirements imposed by state tort law, while 510(k) clearance does not. *See, e.g.*, *Hovey v. Cook Inc.*, 97 F. Supp. 3d 836, 844-46 (S.D. W. Va. Apr. 1, 2015) (rejecting the manufacturer's preemption argument under § 360k and finding that 510(k) clearance of the medical device did not preempt state law tort claims in light of *Lohr* and *Riegel*); *Horrillo v. Cook Inc.*, No. 08-60931-CIV, 2014 WL 8186704, at *3 (S.D. Fla. June 6, 2014) ("[U]nder *Lohr* and *Riegel*, because the stent received FDA approval under the § 510(k) process, Defendant is precluded, as a matter of law, from arguing that Plaintiff's claims are preempted under the express preemption provision set forth in § 360k(a)."); *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513, at *12 (S.D. W. Va. Oct. 18, 2013) ("[T]he 510(k) process does not address product safety and efficacy and therefore is not relevant to Bard's obligations under Georgia state tort law") (citing *Lohr* and *Riegel*); *James v. Diva Int'l, Inc.*, 803 F. Supp. 2d 945, 951 (Mar. 18, 2011) ("The device at issue before the Court was approved by the 'substantially equivalent' process. Defendant argues that this is of no consequence. However, it is worth noting that the Supreme Court has held that this process implements only generally applicable standards and does are not constitute sufficient 'requirements' to trigger preemption under Section 360k(a).") (citing *Lohr*, 518 U.S. at 492-93).[7]

Bard argues that *Lohr* is outdated and does not control this case. Bard notes that *Lohr* concerned a pacemaker cleared by the FDA in 1982, and argues that the 510(k) clearance process was dramatically altered when Congress passed the SMDA in 1990. Doc. 5396 at 19-20. Bard emphasizes that § 12 of the SMDA authorizes the FDA to find

[7] This Court reached a similar conclusion in another case, finding that 510(k) review for a pain pump device did not preempt Arizona negligence and strict liability claims. *Placencia v. I-Flow Corp.*, No. CV10-2520 PHX DGC, 2012 WL 5877624, at *5 (D. Ariz. Nov. 20, 2012).

a device "substantially equivalent" under 510(k) review if it is "as safe and effective as a legally marketed device" and "does not raise different questions of safety and efficacy than the predicate device." PL 101-629 § 12. Bard argues that this consideration of safety and effectiveness was not present in *Lohr*, and, when combined with FDA discretion to require clinical data and testing information, can result in 510(k) clearance procedures that are closer to PMA approval and have preemptive effect. Bard argues that its IVC filters went through a rigorous 510(k) review focused on safety and effectiveness.

The Court does not agree that *Lohr* is outdated. The SMDA did introduce safety and effectiveness considerations into 510(k) review, but only comparatively. Under § 12, the FDA does not make a determination that the device being cleared is safe and effective; it concludes that the device is substantially equivalent to the predicate device. *Id.* True, the FDA may do this by finding that the device "is as safe and effective" as the predicate device, but that is still a comparative exercise. The assumption is that the predicate device is safe and effective enough to be on the market, and that the proposed device, if sufficiently similar, must be so as well. The FDA's 510(k) review "continues to primarily focus on equivalence as opposed to safety." *Hovey*, 97 F. Supp. 3d at 845; *see Riegel*, 552 U.S. at 323.

A 510(k) notice must include information regarding the device, its intended use, and its planned labelling and advertising; whether it is similar to or different from comparable products in commercial distribution; an assurance that the information submitted is truthful and accurate; and any additional information regarding the device requested by the FDA that is necessary to make a finding as to whether or not the device is substantially equivalent to a predicate device. 21C.F.R § 807.87. FDA regulations provide that a 510(k) notice can result in one of several possible outcomes. The FDA can (1) declare the device substantially equivalent to a predicate device, (2) declare the device not substantially equivalent to any predicate device, (3) request additional information, (4) withhold the decision, or (5) advise the applicant that 510(k) clearance is not required. 21 C.F.R. § 807.100(a). Determining that the device is safe and effective is not one of

the available FDA options. Indeed, because the FDA makes no determination regarding the device's safety and effectiveness comparable to PMA approval, FDA regulations specifically prohibit a manufacturer from "misbranding" a 510(k)-cleared device by claiming that it has been "approved" by the FDA. 21 C.F.R. § 807.97.

The PMA process, by contrast, requires a manufacturer to show that its product is sufficiently safe and effective for the U.S. market. *See Buckman*, 531 U.S. at 344-45. If successful, the process results in an FDA finding of safety and effectiveness. Indeed, after PMA approval, the manufacturer cannot change the design, manufacturing process, labeling, or any other attribute of the product that could affect its safety or effectiveness without FDA permission. § 360e(d)(6)(A)(i). The manufacturer must also report to the FDA any information concerning the safety of the device that it learns after receiving approval. § 360i. "[P]remarket approval is focused on safety, not equivalence." *Riegel*, 552 U.S. at 323. It remains fundamentally different from 510(k) review.

The Court cannot conclude that the *Lohr* majority was ignorant of current FDA practices or the 1990 changes made by the SDMA. *Lohr* was decided six years after passage of the SMDA, and any changes to 510(k) review were available to the Court in interpreting Congress's intent. 518 U.S. at 480 n. 4. And yet the Court still concluded that "[t]here is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents." *Id.* at 494. That status quo, *Lohr* noted, "included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design." *Id.*

In short, *Lohr* remains good law, and clearance of a product under 510(k) usually does not preempt state common law claims. But this does not mean that 510(k) clearance can never result in preemption. As Bard notes, the fifth and concurring justice in the *Lohr* majority, Justice Breyer, acknowledged that preemption could occur if specific federal requirements were imposed on a device by the FDA. *Id.* at 503-04. And the

Ninth Circuit has held that state law failure-to-warn claims were preempted for a 510(k) device on which the FDA imposed specific product and disease warning requirements. *See Papike v. Tambrands Inc.*, 107 F.3d 737, 740 (9th Cir. 1997).

How, then, does one identify 510(k) cases where state law claims are preempted? The preemption provision itself provides some helpful guidance. Section 360(k) gives preemptive power only to requirements "applicable to the device." 21 U.S.C. § 360(k). The requirements must be device-specific. In *Lohr*, the Supreme Court also looked to a regulation promulgated by the FDA – 21 C.F.R. § 808.1(d) – for help on the preemptive scope of § 360(k). 518 U.S. at 498-501; *see also id.* at 506-07 (Breyer, J., concurring). That regulation confirms that any preemptive requirement must specifically apply to the device in question:

> State or local requirements are preempted only when the Food and Drug Administration has established *specific counterpart regulations* or there are other *specific requirements applicable to a particular device* under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d) (emphasis added).

Thus, preemption can occur under the 510(k) process only when the FDA has imposed requirements specific to the device in question. More general FDA requirements – what *Riegel* calls "federal manufacturing and labeling requirements applicable across the board to almost all medical devices" – do not preempt state law claims. 552 U.S. at 322. The FDA requirements must do more than reflect "entirely generic concerns about device regulation generally." *Id.* (citations to *Lohr* omitted).

2. Has the FDA Imposed Specific Requirements on Bard Filters?

Bard argues that the FDA has imposed three categories of specific requirements on its filters: (1) special controls, primarily in the form of FDA guidance documents; (2) clinical studies, and testing and design information; and (3) labelling and other information requirements. Doc. 5396 at 24-30. The Court will review each category.

a. Special Controls (Guidance Documents).

Bard relies heavily on the special controls issued by the FDA in connection with 510(k) review of IVC filters generally. One of the special controls is a guidance document issued in November 1999 and titled "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions." 21 C.F.R. § 870.3375(b)(2)(ii); *see* Doc. 5398 ¶ 29, Ex. F. Bard contends that this guidance document is a "specific and detailed directive the FDA issued" for IVC filters. Doc. 5396 at 24. The Court does not agree.

The 1999 guidance document is not a "directive" as Bard claims. It contains this disclaimer: "This document is intended to provide guidance. It represents the [FDA's] current thinking . . . . It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public." Doc. 5398 ¶ 29, Ex. F at 1 n.1.

The document describes itself as a "draft," and makes clear that it does not mandate any particular course of action. IVC filter manufacturers can obtain 510(k) clearance by following "either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness." *Id.* at 1. Thus, manufacturers can choose between following the "recommendations" in the guidance document or alternative approaches.

Bard emphasized at oral argument that the guidance document contains a section on "Filter Performance," but this section simply includes "an outline of the general issues that need to be addressed when seeking premarket clearance for a filter" under 510(k). *Id.* at 3. The section leaves it to the manufacturer to determine what tests or data should be submitted: "Test protocols and acceptance criteria for these tests are the responsibility of the submitter. FDA recognizes that there are many different testing methods that may be used to satisfy the objective." *Id.* The document also includes a suggested general format for filter labels, but no specific regulatory mandate. Manufacturers are free to include other language "specific to [their] particular device design." *Id.* at 9-10. In short, the document leaves much to the discretion of filter manufacturers and provides guidance instead of imposing specific requirements. *See Thompson v. DePuy Orthopaedics, Inc.*,

No. 1:13-CV-00602, 2015 WL 7888387, at *10 (S.D. Ohio Dec. 4, 2015) (noting that the guidance document at issue was "directed mostly to what needs to be submitted to the FDA to facilitate review of the 510(k) application" and contained no "language that mandates anything from the manufacturers").[8]

The two other documents identified by the FDA as special controls for IVC filters are (1) "Use of International Standards Organization's ISO 10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'" and (2) "510(k) Sterility Review Guidance and Revision of 2/12/90 (K90-1)" 21 U.S.C. § 870.3375(b)(1), (b)(2)(i); *see* Doc. 5398 ¶ 28. These documents impose only generic requirements for all implantable medical devices and offer nothing specific to IVC filter design, manufacturing, performance, or labeling. Doc. 7369 at 24 n.17. As *Riegel* noted, "federal manufacturing and labeling requirements applicable across the board to almost all medical devices" do not preempt state common law claims. 552 U.S. at 322. Bard does not contend otherwise.[9]

b. Clinical Studies and Testing and Design Information.

Bard places much emphasis on the fact that clinical studies were required by FDA for 510(k) clearance of the Recovery, G2, and Denali filters. Doc. 5396 at 26-28. But the FDA regulations state that clinical studies can be requested for the purpose of deciding whether a device is substantially equivalent to a predicate device:

> FDA will determine that a device is substantially equivalent to a predicate device using the following criteria: . . .

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[8] *Whitson v. Safeskin*, 313 F. Supp. 2d 473 (M.D. Pa. 2004), is distinguishable because the FDA had established clear and specific requirements for the product in a manual titled "Regulatory Requirements for Medical Gloves." *Id.* at 477.

[9] In its reply brief, Bard discusses internal FDA documents relating to the decision to reclassify IVC filters from Class III to Class II devices. Doc. 7828 at 8-9. Bard notes that the FDA had determined that special controls would provide reasonable assurance of the safety and effectiveness of IVC filters. *Id.* at 9. But this is true for all Class II devices subject to special controls, or at least those reclassified along with IVC filters in 2000. *See* 65 Fed. Reg. 17138-01 (Mar. 31, 200). Bard cites no legal authority for the proposition that mere reclassification, or assignment of special controls to a device cleared through 510(k) review, imposes "requirements" for purposes of § 360k.

> (B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, *including clinical data if deemed necessary by the Commissioner*, that demonstrates that the device is as safe and as effective as a legally marketed device[.]

21 C.F.R. § 807.100(b)(2)(ii)(B) (emphasis added). Two points are relevant. First, requesting such clinical studies is a recognized part of 510(k) review. Second, analysis of the clinical data remains comparative – deciding whether the device is substantially equivalent to the predicate. Bard cites no authority for the proposition that clinical studies required during 510(k) review constitute preemptive requirements for purposes of § 360k. Nor does Bard identify the specific clinical study "requirements" that the Court could compare to the various state law duties to determine whether those duties are preempted.

Bard also notes that the FDA sought information about the testing and design of its IVC filters. *Id.* at 29-30. But the FDA may request additional information, including information concerning safety and effectiveness, to determine "whether or not the device is substantially equivalent to a [predicate] device[.]" 21 C.F.R § 807.87(l); *see James*, 803 F. Supp. 2d at 947-48. Bard has not shown that the FDA's request for testing and design information was outside the scope of a normal 510(k) review or sufficient to make it as rigorous as the PMA process.

Bard suggests that its EVEREST and Denali clinical studies were similar to the rigorous FDA review in *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). Doc. 5396 at 27-28. But *Horn* involved the PMA process, not 510(k) review, a distinction the Third Circuit found critical: "The primary element distinguishing *Lohr* from the instant case is the fact that the [device] received FDA approval through the rigorous § 360e(c) PMA process, not through the § 510(k) 'substantial equivalence' process." *Id.* at 169. After *Riegel*, there is nothing remarkable about the conclusion in *Horn* that "the PMA process imposed requirements that were specifically applicable to the [device], and that triggered preemption under § 360k(a)." *Id.* at 170; *see also Kemp v. Medtronic, Inc.*, 231

F.3d 216, 227-28 (6th Cir. 2000) (finding FDA approval of a PMA supplement to be a "specific federal requirement applicable to the device").

What is more, the heart pump at issue in *Horn* took nearly twenty years to receive FDA approval. 376 F.3d at 169-70. The device underwent ten years of live animal and human cadaver studies before it was granted an investigational device exemption ("IDE") by the FDA in order to permit human clinical trials. *Id.* at 169. The manufacturer then conducted seven years of clinical studies at hospitals, during which it submitted 90 supplements to the FDA. *Id.* The FDA approved the PMA application only after extensive review that spanned three years and included a substantial number of amendments and responses to FDA questions. *Id.* at 170. This process was clearly more rigorous than the 510(k) review of the Bard IVC filters.

Bard cites *Kemp*, 231 F.3d at 227, for the proposition that the IDE clinical trials for the G2 and Denali filters are device-specific and therefore preemptive. Doc. 5396 at 25-26; *see also Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1097 (6th Cir. 1997) (regulations governing investigational devices are device-specific); *Parks v. Howmedica Osteonics Corp.*, No. 8:15-cv-0075-MSS-MAP, 2016 WL 7220707, at *7 (M.D. Fla. Mar. 11, 2016) (IDE approval process is device-specific). But as Plaintiffs correctly note, the G2 and Denali filters were given 510(k) clearance before completion of their respective IDE clinical studies. Doc. 7369 at 28. Moreover, Bard fails to explain how IDE clinical studies conducted as part of the 510(k) substantial equivalence review impose requirements for purposes of § 360k. In other words, even if the FDA required IDE clinical studies, Bard does not describe any resulting § 360k "requirements" that would preempt Plaintiffs' state law claims. *See Oja v. Howmedica, Inc.*, 111 F.3d 782, 787-89 (10th Cir. 1997) (rejecting hip implant manufacturer's arguments that discussions with the FDA to obtain 510(k) clearance including IDE clinical study of cement-less use constituted a specific requirement under *Lohr*).[10]

[10] Bard notes in its reply that clinical trials are required as part of the PMA process. Doc. 7828 at 12 (citing *Scovil v. Medtronic, Inc.*, 995 F. Supp. 2d 1082, 1093 (D. Ariz. 2014)). True, but the rigorous PMA process requires more than clinical trials,

c. Labelling and Other Requirements.

Bard argues that, pursuant 21 U.S.C. § 807.87(e), the FDA required proposed labeling for each Bard IVC filter. Doc. 5396 at 28. But proposed labeling is required for *every* 501(k) submission. Section 807.87 simply describes the information that "[e]ach premarket notification shall contain[.]" These are "federal . . . labeling requirements applicable across the board to almost all medical devices" – requirements which do not preempt state common law claims. *Riegel*, 552 U.S. at 322. They are not like the device- and disease-specific labelling regulation at issue in *Papike*. 107 F.3d at 739-40.

Bard contends that the FDA reviewed and made specific changes to its labels, including adding language regarding bariatric patients and off-label use for the G2 filter and language regarding potential nickel leaching for the Meridian and Denali filters. Doc. 5396 at 28-29. But these changes did not preclude Bard from strengthening its warnings about the risks posed by filter migration, fractures, and perforation. The FDA allows – and in fact encourages – medical device manufactures to "monitor device usage and promptly revise the warning and precautions section [of a label] based on use experience." Doc. 5398 ¶ 38, Ex. G at 11.

Bards notes that the FDA has issued post-SMDA design controls and "good manufacturing" rules, and that these procedures were applied to Bard filters. Doc. 5396 at 22 (citing 21 C.F.R. §820.30; *Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation*, 61 Fed. Reg. 52615 (FDA Oct. 7, 1996)). But Bard fails to explain how these generally applicable rules constitute filter-specific requirements that would preempt Plaintiffs' state law claims.[11]

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see Scovil, 995 F. Supp. 2d at 1088-89, and Bard has not shown that the two IDE clinical trials in this case reflect the rigor that makes FDA premarket approval preemptive.

[11] Bard notes that the FDA has itself indicated that special controls are "regulatory requirements for class II devices." Doc. 5396 at 20 n.16 (citing *FDA Medical Devices, Regulatory Controls*, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm (last updated June 26, 2014). Yet Bard cites no legal authority showing that this statement by the agency is controlling for purposes of preemption. *See Wyeth*, 555 U.S. at 556 (giving no deference to the FDA's mere assertion that state law is preempted where it had enacted no regulation to this effect).

Finally, Bard has submitted more than 800 factual paragraphs to illustrate its extensive communications with the FDA concerning the seven generations of filters at issue in this case. Doc. 5398. But the Court agrees with Plaintiffs' suggestion that these communications merely reflect the back-and-forth of 510(k) review. *See* Doc. 7369 at 25-29. The FDA invoked its regulatory power to require additional information from Bard as a condition for clearance. *See* 21 U.S.C. § 807.87(l). The mere volume of these communications does not show that the FDA's review imposed specific requirements on Bard filters or departed from the 510(k) substantial equivalence standard.[12]

d. *Papike* and *Degelmann* Are Distinguishable.

Bard cites other cases in support of their argument, but the Court finds them distinguishable. *Papike* involved various claims under California law based on injuries the plaintiff sustained when she contracted Toxic Shock Syndrome ("TSS") while using Tampax tampons. 107 F.3d at 738. The Ninth Circuit found the state failure-to-warn claim preempted under § 360k, but not the state claims for negligence, design defect, and breach of warranties. *Id.* at 738, 742-44. Although tampons are Class II devices subject to special controls, *see id.* at 739, this was not the reason for preemption. Rather, *Papike* found that the FDA had promulgated a device-specific regulation "mandating the specific substantive content of the TSS warnings on tampon boxes[.]" *Id.* at 740. The regulation was "not only device-specific (tampons), but also disease-specific (TSS)." *Id.* "This fact distinguishe[d] Papike's case from prior relevant MDA preemption cases, including [*Lohr*]." *Id.*; *see also Rasheed v. Church & Dwight Co.*, No. 5:11CV80, 2012 WL 262619, at *7-8 (E.D. Tex. Jan. 12, 2012) (finding failure-to-warn claim preempted

[12] Bard asserts that its more than 800 paragraphs of facts are both material and undisputed, and that "there is no genuine issue to be tried." Doc. 5398 at 1. But as Plaintiffs correctly note, Bard's statement includes many documents and communications that are not central to the issues in this case – whether the 510(k) review imposed device-specific requirements. And the sheer volume of the submission proves nothing. "Lawyers are tasked with bringing clarity out of chaos, and voluminous filings rarely do that." *State Compensation Ins. Fund v. Drobot*, No. CV 13-0956 AG, 2016 WL 6661338, at *1 (C.D. Cal. Aug. 10, 2016).

where the FDA had issued a specific regulation governing labels for condoms under the same rule subpart as tampons). Bard cites no similar regulation in this case.

Bard's reliance on *Degelmann v. Advanced Medical Optics Inc.*, 659 F.3d 835 (9th Cir. 2011), fares no better. *Degelmann* has been vacated by the Ninth Circuit. *See Placencia*, 2012 WL 5877624, at *5 n.3. Moreover, even if *Degelmann* was still good law, it would not control here. Doc. 5396 at 13, 19. *Degelmann* concerned contact lens solution approved through 510(k) review and the plaintiffs' state-law claims that the solution was mislabeled as "disinfecting." 659 F.3d at 840-42. The FDA had issued a guidance document containing special controls that "mandate" specific stand-alone performance criteria with which manufacturers "must comply" in order to label their contact lens products as a "disinfecting solution." *Id.* at 341-42. The Ninth Circuit found the guidance document to be a specific requirement that the manufacturer undisputedly had met, and held that the state consumer protection and false advertising claims were preempted because they would impose a state requirement in addition to the federal requirements. *Id.* at 842; *see also Tuttle v. CIBA Vision Corp.*, No. 2:05-CV-340 TS, 2007 WL 677134, at *2 (D. Utah Mar. 1, 2007) (finding same guidance document to be a requirement because it is comprehensive and "governs the form, content, and requirements for labels on hydrogen peroxide-based solutions").

e. Federal Requirements Conclusion.

The various FDA reviews of Bard filters do appear to have been more extensive than the 510(k) review at issue in *Lohr*. But Bard has not shown that the reviews imposed device-specific requirements as needed for preemption under § 360(k). The "requirements" identified by Bard are either general, non-preemptive regulations or normal parts of the 510(k) substantial equivalence inquiry.

B. State Requirements.

Lohr instructs courts to undertake a "careful comparison" between the federal requirements at issue and the allegedly preempted state requirements to determine whether they fall within the preemptive scope of § 360k. 518 U.S. at 500. The state law

must be compared to the federal requirements to determine whether the state law establishes requirements "different from, or in addition to," the federal requirements. 21 U.S.C. § 360k(a)(1)(1). But such a comparison is impossible where, as here, no device-specific federal requirements can be ascertained.

The claims asserted by Plaintiffs involve the laws of 50 states – laws the Court must apply in this MDL. *See Am. Life Ins.*, 391 F.3d at 911. Plaintiffs assert multiple causes of action, including claims for strict liability, negligence, breach of warranty, misrepresentation, concealment, and consumer fraud. Doc. 303-1. And yet Bard does not discuss the specific law of any particular state. Bard instead summarizes general state law duties and asserts that those duties impose requirements that are preempted by the requirements imposed on its products through the 510(k) reviews. Doc. 5396 at 30. Such conclusory assertions are insufficient to meet the "careful comparison" required by *Lohr*. For this reason as well, Bard has failed to show that any state law claim is expressly preempted by federal requirements.

V. Implied Preemption.

Because the health and safety of citizens are "'primarily, and historically, matters of local concern,' the 'States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Lohr*, 518 U.S. at 475 (internal citations omitted). Thus, this case presents a classic example of Congress legislating in a field – public health and safety – historically occupied by state police powers. For purposes of implied preemption, therefore, the Court begins with a presumption that state laws are not superseded by the federal statute, a presumption that can be overcome only if preemption "'was the clear and manifest purpose of Congress.'" *Id.* (citation omitted).

Bard contends that Plaintiffs' state law claims are impliedly preempted because it is impossible for Bard to do under federal law what the state laws require. Doc. 5396 at 32-34. The Court does not agree.

Bard relies on two Supreme Court cases that involved the FDCA's labeling requirements for generic prescription drugs, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, —— U.S. ——, 133 S.Ct. 2466 (2013). Under the FDCA, a manufacturer can obtain FDA approval to market a drug only by submitting a new-drug application ("NDA") that is similar to the comprehensive PMA application. 21 U.S.C. § 355(a)-(b); *see Bartlett*, 133 S. Ct. at 2471 (noting that the "process of submitting an NDA is both onerous and lengthy"). The FDA's approval of an NDA includes the approval of the exact text of the proposed label. 21 U.S.C. § 355(d). Generally speaking, a manufacturer may change a drug label only after the FDA approves a supplemental NDA. *See Wyeth*, 555 U.S. at 568. Manufacturers essentially are prohibited from making any change to a generic drug label because the label must at all times be the same as the label of the corresponding brand-name drug. 21 U.S.C. § 314.150(b).

In *Mensing* and *Bartlett*, the Supreme Court found state law failure-to-warn claims preempted by the FDCA because it was impossible under federal law for the manufacturers to do what state law required. *Mensing*, 564 U.S. at 618; *Bartlett*, 133 S. Ct. at 2476-78. As the Court explained: "it was impossible for the [m]anufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Mensing*, 564 U.S. at 618. "Federal law require[d] a very specific label for [the drug], and state law [forbade] the use of that label." *Bartlett*, 133 S. Ct. at 2479.

Bard has identified no similar conflict in this case. Bard asserts that it is prohibited from making changes to their filters without FDA approval, but changing a product is quite different from changing a label. FDA regulations understandably provide that FDA clearance is required when a manufacturer's product "is about to be significantly changed or modified in design, components, method of manufacture, or intended use." 21 C.F.R. § 807.81(a)(3). The Court does not find such a change comparable to the label changes at issue in *Mensing* and *Bartlett*.

Bard also asserts that the FDA prohibits it from making unilateral labeling changes that significantly impact safety and effectiveness without first submitting a new 510(k) notification. Doc. 5396 at 33. In support, Bard cites to an FDA guidance document on when 510(k) submissions are required. *Id.*; Doc. 5398, ¶ 38. The most relevant part of this guidance document for purposes of Plaintiffs' failure-to-warn claims would seem to be the section on changes in warnings or precautions. That section reads as follows:

> In order to facilitate a continuous upgrading in device labelling, manufacturers should monitor device usage and promptly revise the warning and precautions section based on use experience. Events that precipitate changes of this type are routinely reported under the medical device reporting regulation. 510(k)s for such labelling changes are generally unnecessary however, manufacturer's [sic] are encouraged to discuss these situations with [the FDA's Center for Devices and Radiological Health].

Doc. 5398, Ex. G at 11. This guidance clearly does not prohibit Bard from making warning changes without FDA approval.[13]

"Impossibility pre-emption is a demanding defense." *Wyeth*, 555 U.S. at 573. Bard has failed to show that it is impossible to make any labeling changes that may be required by state law. Indeed, Bard acknowledges that the FDA previously has cleared labeling changes to Bard IVC filters and in one instance found that no 510(k) was needed. Doc. 5396 at 33. Bard's impossibility preemption defense is without merit. *See Wyeth*, 555 at 571 ("[A]bsent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."); *Mullins v. Ethicon, Inc.*, 147 F. Supp. 3d 478, 480-85 (S.D. W. Va. 2015) (rejecting impossibility preemption given "Congress' purpose in enacting the 510(k) provision and the absence of any actual conflict between

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[13] The guidance document recently has been superseded. *See* FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device, Guidance for Industry and FDA Staff* (Oct. 25, 2017), *available at* https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514771.pdf (last visited Nov. 16, 2017). The new guidance document also allows for changes in warnings without a 510(k) submission. *See id.* at 22. Moreover, both documents make clear that they are meant to provide guidance only and do not bind the FDA or the regulated industry.

state and federal law"). Bard has also failed to overcome the presumption against preemption that applies to its implied preemption argument.

IT IS ORDERED that Defendants' motion for summary judgment regarding preemption (Doc. 5396) is **denied**.

Dated this 22nd day of November, 2017.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC
Sherr-Una Booker, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00474-PHX-DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters. The MDL Plaintiffs have received implants of Bard IVC filters and claim that they are defective and have caused Plaintiffs to suffer serious injury or death. Plaintiffs assert numerous state law claims and seek both compensatory and punitive damages.

One of the MDL cases is brought by Plaintiff Sherr-Una Booker, who had a Bard filter implanted ten years ago. Plaintiff's case has been selected as one of several

bellwether cases and is set for trial in March 2018. Defendants have filed a motion for partial summary judgment on Plaintiff's claims. Doc. 7456. The motion is fully briefed, and the Court heard oral arguments on November 17, 2017. For reasons set forth below, the Court will grant the motion in part and deny it in part.[1]

I. Factual Background.

[*The factual background section of this order has been redacted because it sets forth Plaintiff's personal medical information protected from public disclosure under the provisions of HIPPA and orders sealing documents in this case. See Doc. 7787. An unredacted version of this order has been filed under seal. See Doc. 8873.*]

II. Plaintiff's Claims.

The Court was assigned this MDL in August 2015. Doc. 1. Three months later, the MDL Plaintiffs filed a long-form master complaint that asserts seventeen causes of action. Doc. 303-1. The master complaint alleges that Bard filters, including the G2, were negligently designed and manufactured and are more dangerous than other IVC filters. The complaint further alleges that Defendants concealed adverse information and otherwise failed to warn about increased risks posed by Bard filters. Defendants dispute the allegations of concealment and high risk levels, contending that complication rates associated with Bard filters are low and comparable to those of other IVC filters.

In her short-form individual complaint filed on February 22, 2016, Plaintiff asserts the following claims under Georgia law: manufacturing defects (Master Complaint Counts I and V), failure to warn (Counts II and VII), design defects (Counts III and IV), failure to recall or retrofit (Count VI), misrepresentation (Counts VIII and XII), negligence per se (Count IX), breach of warranties (Counts X and XI), and punitive

[1] Defendants' motion redacts information concerning Plaintiff's personal medical history. Defendants have filed a sealed unredacted version of the motion. Doc. 7460. The Court will cite to this unredacted document in addressing Defendants' summary judgment arguments.

damages. Doc. 1, CV-16-00474-PHX-DGC. Plaintiff agreed not to pursue the breach of warranty claims before the present motion was filed. Doc. 7460 at 2 n.1.[2]

Defendants seek summary judgment on all claims other than design defects. *Id.* at 1. In her response to Defendants' motion, Plaintiff concedes the insufficiency of her manufacturing defect and failure to recall or retrofit claims. Doc. 8167 at 2 n.1. The Court will grant summary judgment on these claims and the breach of warranty claims.

The remaining claims on which Defendants seek summary judgment are failure to warn, misrepresentation, negligence per se, and punitive damages. The Court will deny summary judgment on the failure to warn and punitive damages claims and grant summary judgment on the claims for misrepresentation and negligence per se.

III. Summary Judgment Standard.

A party seeking summary judgment "bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes over facts that might affect the outcome of the suit will preclude the entry of summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence of the nonmoving party, however, is to be believed, and all justifiable inferences drawn in that party's favor because "[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions[.]" *Id.* at 255.

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[2] Plaintiff does not assert claims for fraudulent concealment (Master Complaint Count XIII), consumer fraud and unfair trade practices (Count XIV), loss of consortium (Count XV), wrongful death (Count XVI), or survival claims (Count XVII). *See id.*; Doc. 303-1 ¶¶ 267-338.

IV. Failure to Warn (Counts II and VII).

The parties agree that Georgia law applies because the alleged injuries occurred in Georgia and Plaintiff lived there when the complaint was filed. Doc. 7460 at 6. To establish a failure to warn claim under Georgia law, "the plaintiff must show the defendant had a duty to warn, the defendant breached that duty and the breach was the proximate cause of the plaintiff's injury." *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999). "[A] manufacturer has a duty to warn of nonobvious foreseeable dangers from the normal use of its product." *Thornton v. E.I Du Pont de Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994) (citations omitted). The duty to warn arises "whenever the manufacturer knows or reasonably should know of the danger arising from the use of its product." *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994). The duty generally is "breached by (1) failing to adequately communicate the warning to the ultimate user or (2) failing to provide an adequate warning of the product's potential risks." *Thornton*, 22 F.3d at 289.

In cases involving prescription drugs and medical devices, Georgia applies the "learned intermediary" doctrine. Under this doctrine, the manufacturer has no "duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and manufacturer." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003) (citing *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1279-80 (11th Cir. 2002)). The manufacturer's warnings to the physician, however, "must be adequate or reasonable under the circumstances of the case." *Id.*

In this case, the G2 filter's Instructions for Use ("IFU") were available to Dr. D'Ayala when he decided to implant the filter in Plaintiff, but he did not have information about any increased risks associated with Bard filters. Doc. 7462-2 at 5-6. Plaintiff alleges that the instructions Bard provided failed to adequately warn about the device's known defects and high complication rates, including the filter's propensity to tilt, fracture, and perforate the IVC. *See* Doc. 303-1 ¶¶ 174-78, 211-16. Plaintiff claims

that this failure to warn constitutes a breach of Bard's duty to adequately warn of the dangers presented by its IVC filters, and proximately caused her injuries. *Id.* ¶¶ 177-81, 215-17. Plaintiff asserts strict liability and negligence claims for the alleged failure to warn. *Id.* ¶¶ 171-81, 202-09; *see* Doc. 1 at 3, CV-16-00474-PHX-DGC.

Defendants contend that the warnings contained in the IFU were adequate as a matter of law because they included the risks of filter movement, fracture, and perforation – the very complications Plaintiff experienced. Doc. 7460 at 9-11. Defendants further contend that proximate cause is lacking because Dr. D'Ayala implanted the G2 filter with knowledge of its potential risks, and there is no evidence that additional warnings would have made him choose a different filter or treatment. *Id.* at 11-12. For purposes of summary judgment, Defendants do not dispute that Plaintiff has presented evidence that Bard knew its IVC filters had complication rates higher than other filters at the time Plaintiff was implanted with the G2 filter. See Doc. 8167 at 4-7.

A. Adequacy of the Warnings.

The IFU for the G2 filter included the following warnings under the bold heading of "Potential Complications":

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.

- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.

- Perforation or other acute or chronic damage of the IVC wall.

- All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava

> filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

Doc. 7457-1 at 2.

Plaintiff concedes that the IFU warned about G2 filters tilting, fracturing, and perforating the IVC, but notes that these complications exist for all IVC filters. Doc. 8167 at 13. Plaintiff argues that the warnings were inadequate because they did not include risk rates or disclose that the risks associated with the G2 filter were higher than those of other filters, including Bard's own Simon Nitonol filter ("SNF"). *Id.* at 12.

Framing the issue as one of duty, Defendants contend that Georgia law imposes no duty on a manufacturer to provide comparative complication rates for its product and those of competitors. Doc. 7460 at 10 n.4; *see* Doc. 7351 at 9-10. Plaintiff counters that the issue is one of breach, not duty, and that there is a triable issue as to whether Defendants' failure to warn about increased risks constitutes a breach of their duty to provide an adequate warning.

This very issue was addressed in *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513 (S.D. W. Va. Oct. 18, 2003). *Cisson*, which applied Georgia law, found that "[a]lthough Bard frames the issue as one of duty, it actually relates to whether Bard's warnings were adequate, which is a question of breach." *Id.* at *7. The Court agrees with this conclusion. Under Georgia law, a duty to warn arises "whenever the manufacturer knows or reasonably should know of the danger arising from the use of its product." *Batten*, 450 S.E.2d at 211. Defendants cite no authority to suggest that this duty arises only on a fact-by-fact basis. The duty arises when dangers are known or reasonably known, and the factual detail that must then be disclosed is then addressed in the adequacy of the disclosure. The duty to warn is breached by "failing to provide an *adequate warning of the product's potential risks*." *Thornton*, 22 F.3d at 289 (emphasis added). After concluding that the question was one of breach, *Cisson* denied judgment on the failure to warn claim, noting that other courts have held that a failure to warn

about the rate or severity of potential injuries raises a jury question over the adequacy of the warnings. 2013 WL 5700513 at *7.

The exact warning at issue in this case was considered recently in *Cason v. C. R. Bard, Inc.*, No. 1:12-CV-1288-HMS, 2015 WL 9913809 (N.D. Ga. Feb. 9, 2015). In *Cason*, as in this case, there was evidence that the G2 filter has a greater propensity to migrate, fracture, and perforate the IVC, and that Bard had knowledge of such increased risks at all relevant times. *Id*. at *4-5. Given this evidence, and the fact that Bard did not warn the plaintiff's doctor about the increased risks, *Cason* concluded that a jury reasonably could find that "the IFU did not contain an adequate warning regarding the G2 Filter." *Id.* at *5. The Court finds this ruling by a Georgia-based federal judge, applying Georgia law, to be highly persuasive. Other cases applying Georgia law have reached similar conclusions. *See Cisson*, 2013 WL 5700513, at *8 (rejecting Bard's argument that warnings were adequate as a matter of law because the IFU identified as a possible adverse reaction each of the complications the plaintiff experienced); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1378 (M.D. Ga. 2010) (rejecting similar argument where the product at issue had a greater propensity to cause complications and was associated with more severe complications than other products); *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1219-20 (11th Cir. 1999) (denying summary judgment on failure to warn claim where Ford's internal documents showed that the Bronco II had a rollover fatality rate more than three times that of other SUVs and the vehicle was rated last in government stability tests).[3]

The Court notes that some of the warnings in the G2 filter's IFU are limited in scope. Although filter movement and migration are identified as known complications,

[3] Defendants asserted at oral argument that *Cisson* and *Cason* were causation cases that did not address duty and breach. To the contrary, *Cisson* made clear that "Bard had a duty to warn about 'any potential dangers that may result' from use of the product[,]'" and that the adequacy of Bard's warnings was a question of breach, not duty. 2013 WL 5700513, at *6-7 (citation omitted). Similarly, *Cason* discussed at length Bard's arguments that it had no duty to warn about increased risks and that its warnings were adequate as a matter of law. 2015 WL 9913809, at *3-6. The issue of causation was discussed only briefly in the last paragraph addressing the failure to warn claim. *Id.* at *6.

the IFU states that "[t]his may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU." Doc. 7457 ¶ 5. The IFU notes that migration of filters to the heart or lungs has been reported, but only "in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens." *Id.* The IFU discloses reports of serious adverse events associated with the use of IVC filters, including death, but only in "morbidly obese patients." *Id.* With respect to filter fracture, the IFU states that most cases had "been reported without any adverse clinical sequelae." *Id.* Plaintiff has presented evidence to the contrary, along with other evidence from which a jury reasonably could find that the warnings contained in the IFU were not adequate. *See Cisson*, 2013 WL 5700513, at *8 (denying motion for judgment as a matter of law where the plaintiff presented evidence that Bard's IFU "downplayed risks by stating that 'potential adverse reactions are those typically associated with surgically implantable materials'").

Defendants argue that they cannot be held liable for failure to warn because the complications Plaintiff experienced – filter tilting, fracture, and perforation – were well documented and known to medical professionals, including Dr. D'Ayala. Doc. 7460 at 10. But this argument misses the mark. As Defendants themselves note, Plaintiff claims that the general warning about complications associated with all IVC filters was inadequate given the G2 filter's *higher* complication rates. *Id.* at 10 n.4. Plaintiff presents evidence that the G2 filter involved substantially greater risks of failure than competitor filters and even Bard's own SNF filter, and that evidence must be accepted as true for purposes of this summary judgment motion.[4]

Defendants state that including warnings about comparative risk rates "is almost certainly precluded by FDA regulations," but they cite no specific regulation in support

[4] Defendants cite *Presto v. Sandoz Pharmaceuticals Corp.*, 487 S.E.2d 70, 73 (Ga. Ct. App. 1997), for the proposition that warning the physician about a product's potential risks is sufficient. Doc. 7460 at 10. The warning, however, must be adequate or reasonable under the circumstances. *See McCombs*, 587 S.E.2d at 595. *Presto* is inapposite because the plaintiffs in that case "ma[de] no argument that the warning given [the doctor] was inadequate." 487 S.E.2d at 73.

of this assertion. Doc. 8574 at 4. The opinion of Defendants' regulatory expert in this regard creates a fact issue for the jury. Defendants' reliance on cases involving prescription drugs is misplaced because those cases concern a specific FDA regulation not applicable to medical devices such as the G2 filter. *See* 21 C.F.R. § 201.57(c)(7) (providing that "any claim comparing [a prescription drug] with other drugs in terms of frequency, severity, or character of adverse reactions must be based on adequate and well-controlled studies").

Defendants contend that Georgia law does not require a manufacturer to provide comparative rates of complications for its products. Doc. 7460 at 10 n.4; Doc. 7351 at 9-10 (citing *Dixie Grp., Inc. v. Shaw Indus. Grp., Inc.*, 693 S.E.2d 888, 892 (Ga. Ct. App. 2010); *Hoffman v. AC & S, Inc.*, 548 S.E.2d 379, 382 (Ga. Ct. App. 2001)). But the cases cited by Defendants concern very different questions: whether a manufacturer can be liable for injuries caused by modifications another party made to its product, *Dixie Grp.*, 693 S.E.2d at 892, and whether a plaintiff must show that it was the defendant's asbestos product – as opposed to an asbestos products generally – that caused her mesothelioma, *Hoffman*, 548 S.E.2d at 382. "Nothing in these cases suggests that a manufacturer's warning is adequate even if it fails to warn that the product is significantly more dangerous than other similar products on the market." *Cason*, 2015 WL 9913809, at *5.

"The general rule in Georgia is that the adequacy of the warning is an issue for the jury [unless] . . . the facts support only one conclusion, that is, the warning and its communication were adequate." *Thornton*, 22 F.3d at 289 (citations omitted). In this case, there are facts from which a jury reasonably could conclude that the warnings contained in the IFU were not "adequate or reasonable under the circumstances of the case." *McCombs*, 587 S.E.2d at 595. The "question that must be answered by the fact finder is whether the warning given was sufficient or was inadequate because it did not 'provide a complete disclosure of the existence and extent of the risk involved.'"

Watkins, 190 F.3d at 1220 (quoting *Thornton*, 22 F.3d at 289); *see Cason*, 2015 WL 9913809, at *4-5; *Cisson*, 2013 WL 5700513, at *7-8.

The Court is not holding, as a matter of Georgia law, that manufacturers must always disclose how the risks of their product compare to the risks of other products. But presumably there is a point where the risks of a product so depart from the norm that a failure to disclose them constitutes an inadequate warning. Whether that point was reached in this case will be for the jury to decide. *See Cason*, 2015 WL 99913809, at *6 (the question "is not whether [D]efendants are able to provide completely up-to-date failure rate comparisons but whether, prior to [Plaintiff's] surgery, they had sufficient information such that they knew or should have known that use of the G2 Filter involved a significantly increased risk of complications as compared to other IVC filters.").

Finally, Defendants contend that summary judgment is warranted because Plaintiff never identifies the precise information the G2 warnings should have contained. Doc. 7460 at 7 (citing *Nolley v. Greenlee Textron, Inc.*, No. 1:06-CV-228-MHS, 2007 WL 5369405, at *7 (N.D. Ga. Dec. 6, 2007)). To the contrary, Plaintiff makes clear that the IFU should have disclosed that the "risks associated with Bard's devices were higher than those of competitor devices or the SNF." Doc. 8167 at 12. The jurors in this case, unlike in *Nolley*, will be presented with proposed warnings and will have a means by which to determine whether the actual warnings were adequate. The Court will consider the parties' proposed jury instructions on the issue of inadequate warnings.

B. Causation.

To prevail on a failure to warn claim, a plaintiff must show that the deficient warning caused her injury. *See Wheat*, 46 F. Supp. at 1362. "Where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that . . . the causal link is broken and the plaintiff cannot recover." *Id.* at 1363.

Defendants contend that any failure to warn Dr. D'Ayala that IVC filters may tilt, fracture, and perforate the IVC wall was not the proximate cause of Plaintiff's injuries because Dr. D'Ayala was aware of these risks when he implanted the G2 filter in Plaintiff. Doc. 7460 at 11. But as explained above, Plaintiff's position is that Defendants failed to warn Dr. D'Ayala about significantly higher complication rates posed by Bard filters. Doc. 8167 at 12-16. The fact that Dr. D'Ayala knew about the existence of complications for all IVC filters does not preclude a showing of causation.

Dr. D'Ayala testified that when he implanted the G2 filter in Plaintiff in June 2007 he was not aware of the high number of adverse events associated with Bard's Recovery filter, the predicate device for the G2. Doc. 8169 ¶ 332-33 (Tr. 33:10-34:5). Nor was he aware of certain Bard documents showing higher complication rates in the Recovery device compared to other filters, including Bard's 2004 crisis management plan, the 2004 health hazard evaluation, the 2005 migration remedial action plan, and the adverse event reports contained in the FDA's Manufacture and User Facility Device Experience ("MAUDE") database. *Id.* ¶¶ 334-336 (Tr. 34:7-40:2). Dr. D'Ayala testified that this information would have influenced his prescribing habits and he would have liked to have known about the high number of adverse events before implanting the G2 filter in Plaintiff. *Id.* Regarding his decision to use a Bard filter, Dr. D'Ayala stated:

> With regards to the Bard filter, would I have used a different device if I knew at the time that the Bard filter was not ideal or as good as some of the other implants? The answer would have to be yes. . . . I would have used a different filter if there was a different filter that I knew of that was better, in terms of its safety profile.

Id. ¶ 338; Docs. 7462-2 at 3, 8169-1 at 32-33 (Tr. 62:25-63:1-9). Consistent with this testimony, Dr. D'Ayala also stated: "If I knew that one filter was better than another, as I said before, absolutely, I would use it." Doc. 8574-1 at 21 (Tr. 76:25-77:2).

Defendants note that Dr. D'Ayala testified that it was "[d]ifficult to say with certainty" whether he would have used a G2 filter in light of internal Bard documents showing higher complication rates because "[it] would depend upon what other filters

[they] had at the time and what their problems would have been." Doc. 7462-2 at 3 (Tr. 63:21-25). Dr. D'Ayala also stated that some filter has to be used in treating difficult patients like Plaintiff, and "it becomes a matter of deciding which filter is best[.]" *Id.* (Tr. 70:20-25). Dr. D'Ayala made clear, however, that information about higher complication rates "would have been a very important piece of information to have, as far as making a decision regarding [Plaintiff]." *Id.* at 4 (Tr. 63:25-64:1-3).

Defendants assert in their reply brief that Dr. D'Ayala's testimony about what he may or may not have done constitutes mere conjecture and speculation that is insufficient to establish causation as a matter of law. Doc. 8574 at 9 & n.8. The Court does not agree. Dr. D'Ayala stated that information about higher complication rates would have influenced his decision, and that he would have used a different device had he known the Bard filter was not as good as other available devices. Doc. 8169-1 at 25-28, 32-33. Indeed, Dr. D'Ayala ultimately stopped using Bard filters due to reports of migration and fragmentation in the MAUDE database and medical literature. *Id.* at 22 (Tr. 31:13-25). Although it is true that Dr. D'Ayala also made more equivocal statements during his deposition, Plaintiff must prove her case by a preponderance of the evidence, not with absolute certainty. Construing Dr. D'Ayala's testimony in Plaintiff's favor, as required at the summary judgment stage, the Court finds that it creates a question of fact on the issue of causation.

Defendants note that Dr. D'Ayala does not rely on a manufacturer's internal documents when deciding which filter to use because such documents are unreliable. Doc. 8574 at 9. But this says nothing about whether Dr. D'Ayala would have implanted a different filter had Defendants warned about higher complication rates in the IFU for the G2 device or in other public documents. Stated differently, the question is not what Dr. D'Ayala would have done had he been aware of Defendant's internal documents, but what he would have done had Defendants provided adequate public warnings.

Under Georgia law, summary judgment is warranted on the issue of causation only where the physician testifies unequivocally that he would have made the same decision

despite the proposed warning. *See Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010) (doctor provided "explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed [anti-depressant]"); *Porter v. Eli Lilly & Co.*, No. 1:06-CV-1297-JOF, 2008 WL 544739, at *13 (N.D. Ga. Feb. 25, 2008) (doctor "unequivocally testified that even if he had read the warning that [plaintiff] asserts should have been given, he still would have prescribed [anti-depressant] to the decedent"). Defendants cite no such testimony from Dr. D'Ayala. *See Watkins v. Eli Lilly & Co.*, No. 1:08-CV-1665, 2010 WL 11493785, at *9 (N.D. Ga. Mar. 31, 2010) (denying summary judgment where the defendant failed to "nail[] this matter down" through deposition testimony).

In summary, the Court concludes that Dr. D'Ayala's testimony "is sufficient evidence of causation at the summary judgment stage, because 'it can be inferred that [he] would not have implanted the G2 Filter'" had he been warned about its higher complication rates. *Cason*, 2015 WL 9913809, at *6 (quoting *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. CV 2:10-cv-01224, 2013 WL 2431975, at *7 (S.D. W. Va. June 4, 2013)); *see Cisson*, 2013 WL 5700513, at *9-10 (denying summary judgment where there was sufficient evidence for a jury to find that the proposed warnings would have prevented the doctor from implanting a Bard device). The Court will deny summary judgment on Plaintiff's failure to warn claims.

V. Misrepresentation (Counts VIII and XII).

"In Georgia, the plaintiff must show actual reliance to support both negligent misrepresentation and fraud claims." *Fanelli v. BMC Software, Inc.*, No. 1:11-cv-00436-JOF, 2013 WL 12190241, at *10 (N.D. Ga. July 29, 2013) (citations omitted). Summary judgment is warranted, Defendants argue, because Plaintiff has presented no evidence showing that either she or Dr. D'Ayala relied on any representation made by Defendants. Docs. 7460 at 7-8 n.3, 8574 at 11. Plaintiff does not address this argument in her response brief (*see* Doc. 8167 at 16-17), and at oral argument stated only that Dr. D'Ayala should have been told about the G2 filter's higher complication rates.

But Plaintiff asserts claims for misrepresentation, not concealment. Doc. 1 at 3-4, CV-16-00474-PHX-DGC. Although Dr. D'Ayala had access to the G2 filter's IFU at the time of Plaintiff's surgery (Doc. 7462-2 at 5-6), Plaintiff has pointed to no evidence showing that Dr. D'Ayala relied on the IFU or any other representation made by Defendants. The Court therefore will grant summary judgment on the misrepresentation claims. *See Celotex*, 477 U.S. at 324 (summary judgment warranted where "the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof").[5]

VI. Negligence Per Se (Count IX).

"In Georgia, 'the violation of a statute, ordinance or mandatory regulation that imposes a legal duty for the protection of others constitutes negligence per se." *Ashton Park Trace Apartments, LLC v. W. Oilfields Supply Co.*, No. 14-CV-4056-MHC, 2015 WL 12469074, at *6 (N.D. Ga. July 16, 2015) (citation omitted). This theory of liability is codified in a Georgia statute: "When the law requires a person to perform an act for the benefit of another or to refrain from doing an act which may injure another, although no cause of action is given in express terms, the injured party may recover for the breach of such legal duty if he suffers damage thereby." Ga. Code Ann. § 51-1-6. Defendants are liable for negligence per se, Plaintiff alleges, because they violated various provisions of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and related regulations by misbranding Bard filters, making false and misleading statements about the filters, failing to notify the FDA when the filters were no longer safe and effective, failing to recall the devices, and not maintaining accurate adverse event reports.

[5] It also appears that, under Georgia law, there are no misrepresentation claims for products liability distinct from failure to warn claims. *See Gaddy v. Terex Corp.*, 1:14-cv-1928-WSD, 2017 WL 3476318, at *5 (N.D. Ga. May 5, 2017); *Brazil v. Janssen Research & Dev. LLC*, 249 F. Supp. 3d 1321, 1340 (N.D. Ga. 2016); *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008). For reasons they did not explain, however, Defendants withdrew this position at oral argument.

Doc. 303-1 ¶ 231.[6]

Defendants argue that this claim is impliedly preempted under 21 U.S.C. § 337(a) because no private right of action exists under the FDCA and all proceedings to enforce or restrain violations of the statute must be brought by the FDA. The Court agrees.

Plaintiff alleges no violation of any state ordinance, regulation, or statute in support of her negligence per se claim. The master complaint cites statutory provisions of more than 40 states, but Georgia is not one of them (*see* Doc. 303-1 at 56-60), and Plaintiff otherwise does not assert statutory claims for consumer fraud or unfair trade practices (*see* Doc. 1 at 4, CV-16-00474-PHX-DGC). Thus, Plaintiff's negligence per se claim exists solely because of alleged violations of the FDCA and its implementing regulations. Doc. 303-1 at 56-60.

Courts have held that "no private right of action exists for a violation of the FDCA." *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002). "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n. 4 (2001). Indeed, § 337(a) expressly provides that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." Thus, "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist." *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011) (citation omitted).

In *Buckman*, the Supreme Court held that a state law claim that a defendant made fraudulent statements to the FDA, in violation of FDCA, was impliedly preempted by § 337(a) because the claim "exist[ed] solely by virtue" of FDCA requirements and therefore "would not be relying on traditional state tort law which had predated the

[6] Specifically, Plaintiff alleges violations of 21 U.S.C. §§ 321, 331, 352, and 21 C.F.R. §§ 1.21, 801, 803, 807, 820. *Id.* at 46-48.

[FDCA]." 531 U.S. at 353. The same is true here. Plaintiff's "claim of negligence per se would not exist prior to the enactment of the FDCA . . . because the claim only alleges violation of that law." *Leonard*, 2011 WL 3652311, at *8. Thus, "as in *Buckman*, Plaintiff's negligence per se claim (or, more appropriately characterized, [her] negligence claim based solely on violations of the FDA-Imposed Requirements or other FDA regulations) is impliedly preempted by the FDCA." *Grant v. Corin Grp. PLC*, No. 3:15-CV-169-CAB-BLM, 2016 WL 447523, at *4 (S.D. Cal. Jan. 15, 2016).

Plaintiff notes that Georgia common law and § 51-1-6 recognize that laws which do not create a private right of action may nonetheless support a claim for damages. Doc. 8167 at 18-19. While it is true that courts generally have allowed a negligence per se claim based on violation of a federal statute, including those that may not expressly provide for a private right of action, "the plain language of § 337(a) and the *Buckman* decision indicate that, where the FDCA is concerned, such claim fails." *Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014). Even if state law recognizes such claims, federal law preempts them.

Plaintiff asserts that *Leonard* is inapposite because, unlike Bard IVC filters, the medical device at issue in *Leonard* had been approved by the FDA through the rigorous premarket approval process. Doc. 8167 at 18. But this was not the basis for *Leonard*'s implied preemption finding. *Leonard* found implied preemption because "all proceedings to enforce or restrain violations of the FDCA 'shall be by and in the name of the United States.'" 2011 WL 3652311, at *7 (quoting § 337(a)). Moreover, preemption under § 337(a) is not limited to devices approved through the premarket approval process. As Defendants note, the device at issue in *Buckman* – like the G2 filter in this case – was cleared for market under 510(k) review. Doc. 8547 at 13.

Plaintiff's reliance on *McClellan v. I-Flow Corp.*, 776 F.3d 1035 (9th Cir. 2015), is misplaced. In that case, the plaintiff's state law failure-to-warn claim had "little to do with direct regulatory interaction with the FDA." 776 F.3d at 1041. The Ninth Circuit found that a negligence per se jury instruction therefore would not usurp the FDA's

exclusive enforcement power over the MDA. *Id.* at 1041 & n.6. In this case, by contrast, Plaintiff's claim exists solely because of alleged FDCA violations and Defendants' interaction with the FDA. The claim clearly is preempted under § 337(a) and *Buckman*.

The Court will grant summary judgment on Plaintiff's negligence per se claim because allowing the claim to go forward would authorize an impermissible action to enforce provisions of the FDCA and its implementing regulations. *See Leonard*, 2011 WL 3652311, at *7-8; *Connelly v. St. Jude Med., Inc.*, No. 5:17-cv-02005-EJD, 2017 WL 361962, at *5 (N.D. Cal. Aug. 23, 2017) (negligence per se claim preempted where it was "based entirely on violations of the FDCA and its implementing regulations"); *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) ("[T]o the extent that Plaintiff seeks to ground her negligence per se and misrepresentation claims on allegations that Defendant violated the FDCA – namely, by selling a misbranded and adulterated product – these claims are impliedly preempted pursuant to 21 U.S.C. § 337(a)."); *see also Mink v. Smith & Nephew*, 860 F.3d 1319, 1330 (11th Cir. 2017) (failure-to-report claim preempted because the duty was owed to the FDA and the "theory of liability is not one that state tort law has traditionally occupied"); *Perez v. Nidek Co.*, 711 F.3d 1109, 1119-20 (9th Cir. 2013) (fraud-by-omission claim "impliedly preempted because it conflicts with the FDCA's enforcement scheme").

This holding is not inconsistent with the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). *Riegel* addressed the scope of 21 U.S.C. § 360k(a), which expressly preempts any state requirement concerning a medical device that "is different from, or in addition to," a federal requirement relating to the device. *Riegel* held that this provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" where "the state duties in such a case 'parallel,' rather than add to, federal requirements." 552 U.S. at 329; *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) ("Nothing in § 360k denies [a state]

the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.").

In this case, however, Plaintiff relies on no parallel state duty in support of her negligence per se claim. The claim cites no Georgia statute. It relies exclusively on alleged violations of the FDCA and its implementing regulations. Plaintiff is not suing under state law for conduct that happens to violate the FDCA, but instead is suing solely "*because* the conduct violates the FDCA." *Perez*, 711 F.3d at 1120 (emphasis in original). Such claims are impliedly preempted under *Buckman* and § 337(a). *See id.*

VII. Punitive Damages.

Under Georgia law, punitive damages may be awarded only where "it is shown by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1(b). Defendants contend that punitive damages are not warranted because there is no evidence they acted with the requisite state of mind and they otherwise complied with all applicable FDA regulations. Doc. 7460 at 14-15. "Compliance with federal regulations, however, is not sufficient to automatically preclude an award of punitive damages." *Cason*, 2015 WL 9913809, at *6 (citing *Cisson*, 2013 WL 5700513, at *11-12). This is particularly true where, as in this case, the device at issue was cleared by the FDA under 510(k) review which focuses primarily on equivalence with other products, not safety. *Cisson*, 2013 WL 5700513, at *12.

Plaintiff claims that Defendants' actions constitute an entire want of care that shows a "conscious indifference" to the dangerous consequences posed by the Recovery filter and its successor, the G2. Doc. 8167 at 19-22. Plaintiff argues that a jury reasonably could award punitive damages because there is evidence that Defendants knew the G2 filter was less safe than the SNF and was failing at a higher rate than competitor devices, and yet never identified the root cause of the failures, provided

adequate warnings, recalled or suspended sales of Bard filters, or implemented known design improvements to address filter migration and perforation. *Id.* at 22.

Under the conscious indifference standard, "[n]umerous Georgia cases have held that punitive damages are available where a manufacturer knows that its product is potentially dangerous and chooses to do *nothing* to make it safer or to warn consumers." *Cisson*, 2013 WL 5700513, at *13 (citations omitted) (emphasis in original). Plaintiff has presented evidence that the Recovery filter had failed internal tests and performed worse than the SNF and competitor devices, and that Bard did not have a full understanding of the filter's design elements before full market release. Doc. 7950 ¶¶ 29, 33-39. Bard began receiving complaints of filter migration and fractures in 2003, and reports of failures resulting in death by April 2004. *Id.* ¶¶ 28, 31. Rather than warning physicians or recalling the filter, Plaintiff alleges that Bard hired a public relations firm to prepare a "Crisis Management Plan" and help Bard "manage controversial or negative stories surrounding the Recovery [filter]." *Id.* ¶ 44, Ex. 38. Bard's bottom line message to the public was: "good filter, severe case, bad outcome, deep regret." *Id.* ¶ 45. Bard viewed this as a "simple story" to be repeated "again and again." *Id.* Significantly, Bard found "[c]omparison with other filters [to be] problematic in many ways," and yet chose to "avoid/downplay this as much as possible." *Id.* Bard continued to sell the Recovery filter even though it had information that the filter was fracturing at a rate higher than other filters, was tilting in nearly a third of all patients, and was significantly less safe than the SNF and competitor devices. *Id.* ¶¶ 47-48, 60-61. Despite this information, Bard provided its employees with a Q&A "script" to follow stating that the Recovery filter's "overall complication rates are comparable to those reported in literature and in the MAUDE database for other IVC filters." *Id.* ¶ 54.

Plaintiff claims that instead of pulling the Recovery filter off the market and starting over, Bard began marketing the next generation G2 filter without adequate testing to determine whether underlying design problems had been fixed. Doc. 8167 at 21-22. By late 2005, Bard was aware that there was no significant change in

perforation rates between the Recovery and G2 filters and that G2 failure rates needed to be investigated. Doc. 7950 ¶¶ 77-78. Bard also was aware that the G2 did not have increased migration resistance over the Recovery and SNF, despite its representations to the contrary. *Id.* ¶ 79. Bard later learned during a clinical study that the G2 tended to tilt at an excessive rate and nearly half the patients had reported an adverse event. *Id.* ¶ 91. With respect to fractures, Bard engineers did not conduct thorough testing because they concluded that the data "would still fall outside the acceptable range" and would not support the G2's "design change as a viable option." *Id.* ¶ 76.

This description of the evidence is made in the light most favorable to Plaintiff, as required for a summary judgment ruling, and is disputed vigorously by Defendants. But if believed by the jury at trial, this evidence is sufficient to support a finding that Defendants "knew the G2 Filter was failing at a significantly higher rate than other IVC filters but did nothing to correct the problem or to warn doctors or patients of the increased risk." *Cason*, 2015 WL 9913809, at *6. A jury reasonably could "conclude that Bard acted with an entire want of care such that Bard was consciously indifferent to the consequences of its actions." *Cisson*, 2013 WL 5700513, at *14; *see Weilbrenner v. Teva Pharms. USA, Inc.*, 696 F. Supp. 2d 1329, 1344 (M.D. Ga. 2010) (punitive damages appropriate for jury consideration where drug manufacturer knew risks of adverse effects in adolescents but did nothing to warn about the dangers); *Mack Trucks, Inc. v. Conkle*, 436 S.E.2d 635, 640 (Ga. 1993) (punitive damages appropriate where truck manufacturer failed to notify purchasers of frame problems); *Ford Motor Co. v. Sasser*, 618 S.E.2d 47, 58 (Ga. Ct. App. 2005) (punitive damages warranted where manufacturer was aware of danger from seat latching system but failed to warn consumers).

Defendants contend that incidents involving the Recovery filter are irrelevant because Plaintiff cannot show a "substantial similarity" between that device and the G2 filter. Doc. 8574 at 14-16. "To show substantial similarity, the plaintiff must come forward with evidence that the other 'incidents share a common design, common defect,

and common causation with the alleged design defect at issue.'" *Chrysler Grp., LLC v. Walden*, 792 S.E.2d 754, 740 (Ga. Ct. App. 2016) (quoting *Colp v. Ford Motor Co.*, 630 S.E.2d 886, 889 (Ga. 2006)). Plaintiff clearly has met this burden.

It is undisputed that the Recovery filter was the predicate device for the G2 and that the two filters share a common design. Indeed, Defendants themselves acknowledge that they filed a 510(k) notice in March 2005 "seeking clearance for a modified Recovery Filter (subsequently known as the G2 Filter)[.]" Doc. 5396 at 8. The FDA cleared the G2 as a permanent filter after finding it to be "substantially equivalent" to the Recovery filter. *Id.* at 9. A device is "substantially equivalent" to a predicate device if it has the same intended use and the same technological characteristics as the predicate device, or any differences do not raise different safety issues. 21 U.S.C. § 360c(i)(1)(A).

What is more, Plaintiff has presented evidence that the two devices share common design defects that have caused similar adverse events, namely, filter migration, fracture, and perforation resulting in serious injury or death. Contrary to Defendants' contention, Plaintiff has shown a "substantial similarity" between the Recovery and G2 filters.[7]

Defendants contend that punitive damages are not warranted for any failure to make design changes before June 2007 given the extensive design, testing, and regulatory clearance processes that were required before any design changes could be implemented. Doc. 8574 at 17. But the same cannot be said about providing warnings for Bard filters. Indeed, Defendants acknowledge that the FDA previously has cleared labeling changes to Bard IVC filters and in one instance found that no 510(k) clearance was even needed. Doc. 5396 at 33.

Defendants claim that Georgia courts have denied punitive damages in circumstances more egregious than those alleged here. Doc. 8574 at 18. The cases Defendants cite, however, are distinguishable. *See Hernandez v. Crown Equip. Corp.*, 92 F. Supp. 3d 1325, 1357 (M.D. Ga. 2015) (forklift manufacturer was not consciously

[7] Defendants' reliance on *Ray v. Ford Motor Co.*, 514 S.E.2d 227 (Ga. Ct. App. 1999), is misplaced. The plaintiff in that case did not argue that the prior incidents were similar to her accident, and the evidence otherwise was unreliable. *Id.* at 231.

indifferent to the risk of leg or foot injuries in part because it "placed warnings on the forklifts and in the operator's manual relating to this danger"); *Moore v. Wright Tech., Inc.*, No. 1:14-cv-62, 2016 WL 1298975, at *6 (S.D. Ga. Mar. 31, 2016) (summary judgment warranted where the plaintiff cited no legal authority and merely referenced the defendant's misconduct in general in support of punitive damages); *Stuckey v. N. Propane Gas Co.*, 874 F.2d 1563, 1575 (11th Cir. 1989) (affirming denial of motion to add punitive damages claim at trial and merely noting that the evidence did not justify an award of punitive damages).

The Court will deny summary judgment on Plaintiff's claim for punitive damages.

IT IS ORDERED:

1. Defendants' motion for partial summary judgment (Doc. 7456) is **granted in part** and **denied in part**. The motion is granted with respect to Plaintiff's claims for manufacturing defects (Counts I and V), failure to recall or retrofit (Count VI), misrepresentation (Counts VIII and XII), negligence per se (Count IX), and breach of warranty (Counts X and XI). The motion is denied with respect to Plaintiff's claims for failure to warn (Counts II and VII) and punitive damages. These claims, along with the design defect claims (Counts III and IV), remain for trial.

2. A final pretrial conference is set for **February 23, 2018 at 2:00 p.m.** The trial is set to begin on **March 13, 2018 at 9:00 a.m**. *See* Docs. 8104, 8858.

Dated this 22nd day of November, 2017.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC
Doris Jones and Alfred Jones, Sr., a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00782-PHX-DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters. The MDL Plaintiffs have received implants of Bard IVC filters and claim that they are defective and have caused Plaintiffs to suffer serious injury or death.

The case brought by Doris and Alfred Jones has been selected as one of several bellwether cases and is set for trial in May 2018. Defendants have filed a motion for partial summary judgment. Doc. 7351. The motion is fully briefed, and the parties agree

that oral argument is not necessary. For reasons set forth below, the Court will grant the motion in part and deny it in part.[1]

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. An IVC filter is a small metal device implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard IVC filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali. They are spider-like devices that have multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with elastic hooks that attach to the IVC wall and curved arms that serve to catch or break up blood clots. Each of these filters is a variation of its predecessor.

The MDL Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have higher risks of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs further allege that Bard failed to warn physicians and patients about these higher risks. Plaintiffs assert a host of state law claims and seek both compensatory and punitive damages. Defendants dispute Plaintiffs' allegations, contending that Bard filters are safe and effective, that their complication rates are low and comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters.

II. Plaintiffs Doris and Alfred Jones.

In August 2010, before gastrointestinal surgery, Doris Jones was implanted with an Eclipse filter due to recurrent deep vein thrombosis. Dr. Anthony Avino implanted the filter without incident. In April 2015, Mrs. Jones went to the emergency room with complaints of lightheadedness and arm pain. A chest scan revealed a fractured filter limb

[1] The motion redacts certain information concerning Mrs. Jones's personal medical history. Doc. 7531. Defendants have filed an unredacted version of that brief under seal. Doc. 7354. The Court will cite to the redacted motion in addressing the summary judgment arguments.

that had embolized in the right pulmonary artery. The filter was removed but the fractured limb remains in place.

Mrs. Jones and her husband assert various claims under Georgia law, some of which have been withdrawn. The following claims remain: failure to warn (Counts II and VII), design defects (Counts III and IV), misrepresentation (Counts VIII and XII), negligence per se (Count IX), fraudulent concealment (Count XIII), consumer fraud and unfair trade practices (Count XIV), loss of consortium (Count XV), and punitive damages. *See* Doc. 364 (master complaint); Doc. 1, CV-16-00782-PHX-DGC (short-form complaint).[2]

Defendants seek summary judgment on the failure to warn, misrepresentation, negligence per se, consumer fraud and unfair trade practices, and punitive damages claims. Doc. 7351 at 3. Plaintiffs concede that summary judgment is proper on the consumer fraud and unfair trade practices claim. Doc. 7943 at 2 n.1. The Court will grant summary judgment on that claim and the misrepresentation and negligence per se claims. The Court will deny summary judgment on the failure to warn and punitive damages claims.[3]

III. Summary Judgment Standard.

A party seeking summary judgment "bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v.*

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[2] The master complaint is the operative pleading for most of the cases in this MDL. It was created for the sake of convenience and serves as a long-form complaint giving notice, pursuant to Rule 8, of the allegations that Plaintiffs assert generally. Plaintiff-specific allegations are contained in individual short-form complaints or certain complaints served on Bard before the filing of the master complaint. *See* Doc. 249 at 6. Plaintiffs also provide Bard with profile forms and fact sheets that describe their individual conditions and claims. *See* Doc. 365.

[3] Defendants do not seek summary judgment on the claims for design defect (Counts III and IV), fraudulent concealment (Count XIII), and loss of consortium (Count XV). Plaintiffs withdrew the followings claims before Defendants moved for summary judgment: manufacturing defect (Counts I and V), negligent failure to recall or retrofit (Count VI), and breach of warranty (Counts X and XI). *See* Doc. 7351 at 2. Plaintiffs do not assert claims for wrongful death or survival (Counts XVI and XVII).

Catrett, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes over facts that might affect the outcome of the suit will preclude the entry of summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence must be viewed in the light most favorable to the nonmoving party, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), and all justifiable inferences are drawn in that party's favor because "[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions," *Anderson*, 477 U.S. at 255.

IV. Failure to Warn (Counts II and VII).

Georgia law applies in this case because the alleged injuries occurred in Georgia and Plaintiffs lived there when their complaint was filed. Doc. 7351 at 5; Doc. 1 ¶¶ 4-6, CV-16-00782-PHX-DGC. To establish a failure to warn claim under Georgia law, "the plaintiff must show that the defendant had a duty to warn, the defendant breached that duty and the breach was the proximate cause of the plaintiff's injury." *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999). "[A] manufacturer has a duty to warn of nonobvious foreseeable dangers from the normal use of its product." *Thornton v. E.I. Du Pont de Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994). The duty to warn arises "whenever the manufacturer knows or reasonably should know of the danger arising from the use of its product." *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994). The duty may be breached in two ways: "(1) failing to adequately communicate the warning to the ultimate user or (2) failing to provide an adequate warning of the product's potential risks." *Thornton*, 22 F.3d at 289.

In cases involving medical devices, Georgia applies the "learned intermediary" doctrine. Under this doctrine, the manufacturer has no "duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor,

who acts as a learned intermediary between the patient and manufacturer." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003) (citing *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1279-80 (11th Cir. 2002)). The manufacturer's warnings to the physician, however, "must be adequate or reasonable under the circumstances of the case." *Id.*

In this case, Plaintiffs allege that Bard failed to adequately warn physicians about the known defects and higher complication rates associated with Bard filters. Doc. 364 ¶¶ 174-78, 211-16. Plaintiffs claim that this failure constitutes a breach of Bard's duty to warn and proximately caused their injuries. *Id.* ¶¶ 177-81, 215-17. Plaintiffs assert strict liability and negligence claims for the alleged failure to warn. *Id.* ¶¶ 171-81, 202-09; *see* Doc. 1 at 3, CV-16-00782-PHX-DGC.

Defendants contend that proximate cause is lacking because Dr. Avino did not read the Eclipse filter's instructions for use ("IFU") and had actual knowledge of the risk of fracture. Doc. 7351 at 6-7. Defendants further contend that the warnings provided with the Eclipse filter were adequate because they included the complication experienced by Mrs. Jones. *Id.* at 8-11. The Court will address each argument.

A. Causation.

1. Failure to Read the Eclipse IFU.

Defendants rely on *Wilson Foods Corp. v. Turner*, 460 S.E.2d 532, 534 (Ga. Ct. App. 1995), for the proposition that "failure to read product instructions . . . will prevent a plaintiff from recovering on a claim grounded on failure to provide adequate warning of the products' potential risk." Doc. 7351 at 6. Defendants contend that Dr. Avino did not read the Eclipse IFU before implanting the device in Mrs. Jones, and Plaintiffs therefore cannot show that any warning inadequacy proximately caused their injuries. *Id.*

But the duty to warn is breached not only by having a deficient warning, but also by "failing to adequately communicate the warning to the ultimate user." *Thornton*, 22 F.3d at 289. Indeed, *Wilson* makes clear that failure to read instructions "'does not bar recovery where the plaintiff is challenging the adequacy of the efforts of the manufacturer or seller to communicate the dangers of the product to the buyer or user.'"

460 S.E.2d at 534 (quoting *Thornton*, 22 F.3d at 290). Plaintiffs bring such a challenge in this case.

Plaintiffs claim that the instructions contained in the IFU were inadequate, and that Bard otherwise failed to communicate sufficient warnings to physicians. Specifically, Plaintiffs allege that Bard breached its duty to warn by not "providing instructions for safe use" or "communicating the information and dangers" about Bard filters to physicians. Doc. 364 ¶¶ 181, 216. Plaintiffs note that medical device warnings are provided in various ways, including "dear doctor" letters, product pamphlets, and statements by the company sales representatives. Doc. 7943 at 14 (citing *Allen v. Belinfante*, 458 S.E.2d 867, 869 (Ga. Ct. App. 1995) (assessing doctor's awareness of "dear doctor" letters and other sources of information about potential risks in determining liability for failure to warn claim)); *see PLIVA, Inc. v. Mensing*, 564 U.S. 604, 615 (2011) (noting that manufacturers provide warnings through dear doctor letters).

Given Plaintiffs' claim that Bard breached its duty to warn by failing to adequately communicate warnings to physicians through means other than IFUs, the fact that Dr. Avino may not have read the Eclipse IFU is not dispositive on causation. *See Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1247 (N.D. Ga. 2002) ("A plaintiff's failure to read a warning will not . . . bar recovery as to the first prong of the test: namely, where the plaintiff is challenging the *adequacy* of the defendant's efforts to communicate the dangers of the product to the user[.]" (citing *Wilson*, 460 S.E.2d at 534)); *In re Stand 'n Seal Prods. Liab. Litig.*, No. 1:07MD1804-TWT, 2009 WL 2145911, at *6 (N.D. Ga. July 15, 2009) (denying summary judgment where the plaintiffs did not read the warning label but claimed that the manufacturer's efforts to communicate the dangers were inadequate (citing *Wilson*)); *Mizell v. Pilgrim's Pride Corp.*, No. CV 509-064, 2012 WL 130056600, at *5 (S.D. Ga. Mar. 14, 2012) (finding the failure to read a warning not dispositive where the plaintiff challenged the manufacturer's communication of the warning (citing *Wilson*)); *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2007 WL 4117201, at *2 (M.D. Fla. Nov. 6, 2007) (denying summary judgment

where the plaintiffs alleged that the manufacture failed to communicate drug risks in dear doctor letters and promotional materials used by sales representatives); *see also Flowers v. Eli Lilly & Co.*, No. 3:14-cv-0094-LHR-VPC, 2015 WL 12622058, at *3 (D. Nev. July 10, 2015) (manufacturer met its duty to communicate potential risks by sending dear doctor letters to physicians).[4]

2. Knowledge of the Risk.

Defendants note that the causal link is generally broken where the treating physician has actual knowledge of the risk. Doc. 7351 at 7. Defendants contend that proximate causation is lacking in this case because Dr. Avino was aware of IVC filter complications – including fracture – before implanting the Eclipse filter in Mrs. Jones. *Id.* Defendants further contend that Bard cannot be liable for failure to warn because IVC filter complications are well known by the medical community. *Id.* at 9.

Plaintiffs concede that Bard warned Dr. Avino and other physicians about filter complications generally, but contend that the warnings were inadequate because Bard did not disclose that the risk of complications for the Eclipse filter was *higher* than those of other IVC filters, including Bard's own Simon Nitinol Filter ("SNF"). Doc. 7943 at 6-7, 10-11. Plaintiffs present evidence that the Eclipse and its predecessor devices, the Recovery and G2 line of filters, involved substantially greater risks of fracture than other IVC filters. Doc. 7943 at 4. Plaintiffs claim that Dr. Avino was not aware of the higher risks, and that he would have wanted to know this information when deciding whether to implant the Eclipse filter in Mrs. Jones. *Id.* Dr. Avino testified that his initial understanding was that the fracture rates for Bard filters were very low, and he learned

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[4] The parties dispute whether Dr. Avino actually read the Eclipse IFU. Dr. Avino testified that he sometimes reads IFUs, but does not read them on every package where the product is the same, and that he does not specifically recall if he read the Eclipse IFU. Doc. 7357-3 at 5. Plaintiffs contend that Dr. Avino was aware of the warnings in the Eclipse IFU because he read those very warnings for Bard's G2 line of filters. Doc. 7943 at 13. The Court finds that there is a genuine factual dispute on this issue that is best resolved by the jury. *See In re Stand 'n Seal*, 2009 WL2145911, at *6 (finding triable issue where the plaintiff could not remember whether he read the warnings and noting that "[i]ssues of causation are for the jury to resolve and should not be determined by a trial court as a matter of law except in plain and undisputed cases").

only during the past several years that the rates were higher. Doc. 7974 at 42-43. He further stated that the time period in which he treated Mrs. Jones "predates the peak of his concern and the release of the warnings about the complications of filters." *Id.* at 33-34. He made clear that if Bard knew about higher complication rates associated with its filters before Mrs. Jones's surgery, he would have wanted to know that information. *Id.* at 34, 45-46.

Construed in Plaintiffs' favor, Dr. Avino's testimony is sufficient evidence of causation at the summary judgment stage. A jury reasonably could infer that he would not have implanted the Eclipse filter in Mrs. Jones had he been warned about higher fracture rates. *See In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. CV 2:10-cv-01224, 2013 WL 2431975, at *7 (S.D. W. Va. June 4, 2013) (denying summary judgment where the doctor never explicitly stated that he would not have used Bard's product had he been provided additional warnings, but explained that the information would have been "helpful" and "nice to have"); *Cason v. C. R. Bard, Inc.*, No. 1:12-CV-1288-HMS, 2015 WL 9913809, at *6 (N.D. Ga. Feb. 9, 2015) (denying summary judgment where the doctor stated that "he would have wanted to know if the G2 Filter had a significantly higher risk of complications than other IVC filters"). Georgia law is clear that summary judgment is warranted on the issue of causation only where the physician testifies unequivocally that he would have made the same decision despite the proposed warning. *See Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010) (doctor provided "explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed [the anti-depressant]"); *Porter v. Eli Lilly & Co.*, No. 1:06-CV-1297-JOF, 2008 WL 544739, at *13 (N.D. Ga. Feb. 25, 2008) (doctor "unequivocally testified that even if he had read the warning that [plaintiff] asserts should have been given, he still would have prescribed [the anti-depressant] to the decedent"). Defendants cite no such testimony from Dr. Avino.[5]

[5] Defendants assert in their reply that Plaintiffs did not ask Dr. Avino during his

Defendants' reliance on *In re Wright Medical Technology Inc.*, 127 F. Supp. 3d 1306 (N.D. Ga. 2015), is misplaced. Doc. 7351 at 7. The undisputed evidence in that case showed that the physician educated himself about product risks by reviewing the medical literature, had never read package insert warnings for any device he implanted, and did not have access to the insert prior to the plaintiff's surgery because it was in a sterile package. 127 F. Supp. 3d at 1359-60. Moreover, the failure to warn claim was governed by Utah law, not the law of Georgia. *See id.* at 1358.

Defendants' reliance on *Wheat* and *Ellis* fares no better. Doc. 7351 at 7-9. Each treating physician in *Wheat* unequivocally testified that "he was aware of the risks associated with spinal implant surgery, that such risks were well known in the medical community, and that he would have taken the same course of action in spite of the information [the plaintiffs] contend[ed] should have been provided." 46 F. Supp. at 1363. *Ellis* held that a medical device manufacturer has no duty to warn anyone other than the learned intermediary, and granted summary judgment because it was undisputed that this duty had been met. 311 F.3d at 1281-83 ("[W]e conclude that Georgia's learned intermediary rule controls this case, [and] that the defendants adequately warned the doctors . . . of the damages of third-party [pain pump] activation[.]").[6]

B. Adequacy of the Warnings.

The Eclipse IFU included the following warnings:

> Filter fracture is a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with

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deposition whether a different warning would have mattered. Doc. 8391 at 10. But apparently neither did Defendants. Absent unequivocal testimony in this regard, summary judgment is not warranted. *See Watkins v. Eli Lilly & Co.*, No. 1:08-CV-1665, 2010 WL 11493785, at *9 (N.D. Ga. Mar. 31, 2010) (denying summary judgment where the defendant failed to "nail[] this matter down" through deposition testimony).

[6] Defendants assert in their reply that Plaintiffs have presented no evidence that the Eclipse filter fractured at a significant enough rate to render Bard's warnings about fracture inadequate. Doc. 8391 at 9. Plaintiffs present evidence of significantly higher fracture rates for the G2 filter, claim that the Eclipse is essentially the same as the G2, and dispute whether electropolishing of the Eclipse was effective in reducing fracture rates experienced by the G2. *Id.* at 4 n.3, 16. Given this evidence, the fracture rate for Eclipse filters is an issue for the jury.

> vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
>
> . . . .
>
> [T]he above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

Doc. 7352-1. Defendants contend that these warnings were adequate as a matter of law because they included a risk of fracture – the very complication experienced by Mrs. Jones. Doc. 7351 at 8-9. Plaintiffs argue that the warnings were inadequate because they did not include risk rates or disclose that the risks associated with the Eclipse filter were higher than those for the SNF and other IVC filters. Doc. 7943 at 10. Anticipating this argument, Defendants counter that Georgia law imposes no duty on a manufacturer to provide comparative risk rates for its product and those of competitors. Doc. 7351 at 9-10.

The Court addressed this issue in ruling on Defendants' summary judgment motion in the Booker case. Agreeing with the decisions in *Cason* and *Cisson*, which applied Georgia law, the Court found that whether Bard's warnings were adequate is a question of breach, not duty. Doc. 8874 at 6-7 (citing *Cason*, 2015 WL 9913809, at *4-5; *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513, at *7 (S.D. W. Va. Oct. 18, 2003)). The Court reaches the same conclusion in this case.

The Court further finds that the alleged failure to warn about the rate of complications raises a jury question over the adequacy of Bard's warnings. "The general rule in Georgia is that the adequacy of the warning is an issue for the jury [unless] . . . the facts support only one conclusion, that is, the warning and its communication were adequate." *Thornton*, 22 F.3d at 289 (citations omitted). The evidence presented in this case, when construed in the light most favorable to Plaintiffs, *see Matsushita*, 475 U.S. at 587, supports a finding that Bard's warnings for the Eclipse filter were not "adequate

or reasonable under the circumstances of the case." *McCombs*, 587 S.E.2d at 595. The "question that must be answered by the fact finder is whether the warning given was sufficient or was inadequate because it did not 'provide a complete disclosure of the existence and extent of the risk involved.'" *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1220 (11th Cir. 1999) (quoting *Thornton*, 22 F.3d at 289). In short, whether the warnings should have included comparative risk rates will be for the jury to decide. *See Cason*, 2015 WL 9913809, at *5 ("Given . . . that defendants did not warn Mrs. Cason's doctor about any increased risk associated with the G2 Filter, a reasonable fact finder could conclude that the IFU did not contain an adequate warning[.]"); *Cisson*, 2013 WL 5700513, at *7 (failure to warn about "the rate or severity of potential injury creates a jury question over the adequacy of warnings"); *Watkins*, 190 F.3d at 1219-20 (denying summary judgment on failure to warn claim where Ford's internal documents showed that the Bronco II had a rollover fatality rate more than three times that of other SUVs and the vehicle was rated last in government stability tests); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1378 (M.D. Ga. 2010) (finding a triable issue on adequacy of warning where the product had a greater propensity to cause complications and was associated with more severe complications than other products).

Defendants contend that Georgia law does not require a manufacturer to provide comparative rates of complications for its products. Doc. 7351 at 9-10 (citing *Dixie Grp., Inc. v. Shaw Indus. Grp., Inc.*, 693 S.E.2d 888, 892 (Ga. Ct. App. 2010); *Hoffman v. AC & S, Inc.*, 548 S.E.2d 379, 382 (Ga. Ct. App. 2001)). But as previously explained (Doc. 8874 at 9), the cases cited by Defendants concern very different questions: whether a manufacturer can be liable for injuries caused by modifications another party made to its product, *Dixie Grp.*, 693 S.E.2d at 892, and whether a plaintiff must show that it was the defendant's asbestos product – as opposed to asbestos products generally – that caused her mesothelioma, *Hoffman*, 548 S.E.2d at 382. "Nothing in these cases suggests that a manufacturer's warning is adequate even if it fails to warn that the product is

significantly more dangerous than other similar products on the market." *Cason*, 2015 WL 9913809, at *5.

Defendants state in their reply that including warnings about comparative risk rates "is almost certainly precluded by FDA regulations," but they cite no specific regulation in support of this assertion. Doc. 8391 at 6. Defendants' reliance on cases involving prescription drugs is misplaced because those cases concern a specific FDA regulation not applicable to medical devices such as the Eclipse filter. *See* 21 C.F.R. § 201.57(c)(7) ("The requirements in this section apply only to prescription drug products[.]").

Defendants further state that providing comparative warnings would be impossible because the data for defining actual rates is inherently unreliable and ever-changing. Doc. 8391 at 6-7. The question, however, is not whether Defendants were able to provide completely accurate and up-to-date failure rate comparisons, but whether, prior to Mrs. Jones's surgery, "they had sufficient information such that they knew or should have known that use of the [Eclipse filter] involved a significantly increased risk of [fracture] as compared to other IVC filters." *Cason*, 2015 WL 9913809, at *6. As explained above, a jury reasonably could conclude that Defendants had such information and therefore had a duty to warn Dr. Avino of the increased risk.

Finally, Defendants contend that summary judgment is warranted because Plaintiffs have identified no alternative warning. Doc. 8391 at 8-9 (citing *Nolley v. Greenlee Textron, Inc.*, No. 1:06-CV-228-MHS, 2007 WL 5369405, at *6 (N.D. Ga. Dec. 6, 2007)). To the contrary, Plaintiffs make clear Bard should have disclosed to implanting physicians such as Dr. Avino that Bard filters (including the Eclipse) fractured at rates significantly higher than the SNF and competitor filters. Doc. 7943 at 2, 7, 10. The jurors in this case, unlike in *Nolley*, will be presented with proposed warnings and will have a means by which to determine whether the actual warnings were adequate.

In summary, there are triable issues as to whether Bard's warnings in this case

were adequate and whether Bard sufficiently communicated the warnings to Dr. Avino. The Court will deny summary judgment on Plaintiffs' failure to warn claims (Counts II and VII).

V. Misrepresentation (Counts VIII and XII).

Defendants contend that the misrepresentation claims fail for the same reasons the failure to warn claims fail, namely, that Bard provided adequate warnings and the alleged failure to warn could not be the proximate cause of Plaintiffs' injuries. Doc. 7351 at 6. For reasons explained above, the failure to warn claims survive summary judgment.

Defendants also note, however, that Georgia does not recognize a claim for misrepresentation apart from a failure to warn claim in products liability cases. *Id.* at 6 n.2.[7] Defendants rely on two district court cases: *Brazil v. Janssen Research & Development, LLC*, 249 F. Supp. 3d 1321, 1340 (N.D. Ga. 2016), and *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008). In *Swicegood*, the plaintiff brought a products liability action after she allegedly suffered an adverse reaction to a generic prescription drug. 543 F. Supp. 2d at 1353. The plaintiff alleged, among other things, that the defendants knew that long-term use of the drug posed a greater risk of causing the adverse reaction than they disclosed to the FDA or the public. *Id.* The plaintiff asserted several claims under Georgia law, including strict products liability, failure to warn, and misrepresentation. *Id.* at 1353-57. The court concluded that "misrepresentation claims against a manufacturer properly collapse into the failure to warn claims." *Id.* at 1357. Absent clear Georgia precedent, the court declined "to recognize the viability of misrepresentation claims distinct from products liability or failure to warn claims." *Id.*

The court in *Brazil* reached a similar conclusion. The court dismissed the plaintiff's

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[7] Defendants made the same argument in seeking summary judgment on the misrepresentation claims in the Booker case (Doc. 7460 at 7-8 n.3), but withdrew this position at oral argument in Booker for reasons they did not explain (*see* Doc. 8874 at 14 n.5).

misrepresentation claim, noting that *Swicegood* had "determined that there [are] no misrepresentation claims for products liability distinct from failure to warn claims." 249 F. Supp. 3d at 1340; *see Gaddy v. Terex Corp.*, 1:14-cv-1928-WSD, 2017 WL 3476318, at *5 (N.D. Ga. May 5, 2017) (same).

The Court finds these rulings by Georgia-based federal judges, applying Georgia law, to be persuasive. *See also In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 856 F. Supp. 2d 904, 910 (E.D. Ky. 2012) (citing *Swicegood* and noting that "courts in many states have expressly rejected the argument that misrepresentation claims are distinct from product liability or failure-to-warn claims" (citations omitted)). The Court will grant summary judgment on the misrepresentation claims (Counts VII and XII).

Plaintiffs note that *Potts v. UAP-GA AG CHEM, Inc.*, 567 S.E.2d 316, 318 (Ga. Ct. App. 2002), contemplated that a misrepresentation claim could be distinct from a failure to warn claim in a products liability suit. But the misrepresentation claim in *Potts* was truly distinct. It was asserted against the decedent's former employer for allegedly misrepresenting to a physician that the decedent was not exposed to the chemicals at issue. 567 S.E.2d at 319-20. Unlike the misrepresentation claims asserted in this case, the claim in *Potts* was distinct from the strict liability and failure to warn claims asserted against the manufacturer. *Id.* ("Here the misrepresentation was to LeBlanc's physician, on whom LeBlanc was relying for treatment. Through the misrepresentation, [the employer] induced the physician to discount the possibility of chemical poisoning and to change LeBlanc's treatment, on which treatment LeBlanc was relying for his physical recovery.").[8]

VI. Negligence Per Se (Count IX).

"In Georgia, 'the violation of a statute, ordinance or mandatory regulation that

[8] Defendants assert in their reply that even if Georgia recognized separate products liability misrepresentation claims, Plaintiffs offer no evidence of the required elements, such as scienter and justifiable reliance. Doc. 8391 at 12. The Court will not grant summary judgment based on an argument raised for the first time in a reply brief. *See Zamani v. Carnes*, 491 F.3d 990, 997 (9th Cir. 2007).

imposes a legal duty for the protection of others constitutes negligence per se.'" *Ashton Park Trace Apartments, LLC v. W. Oilfields Supply Co.*, No. 14-CV-4056-MHC, 2015 WL 12469074, at *6 (N.D. Ga. July 16, 2015) (citation omitted). This theory of liability is codified in a Georgia statute: "When the law requires a person to perform an act for the benefit of another or to refrain from doing an act which may injure another, although no cause of action is given in express terms, the injured party may recover for the breach of such legal duty if he suffers damage thereby." Ga. Code Ann. § 51-1-6.

Plaintiffs allege that Defendants are liable for negligence per se because they violated various provisions of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and related regulations, by misbranding Bard filters, making false and misleading statements about the filters, failing to notify the FDA when the filters were no longer safe and effective, failing to recall the devices, and not maintaining accurate adverse event reports. Doc. 364 ¶ 231.[9] This claim is impliedly preempted under 21 U.S.C. § 337(a), Defendants argue, because no private right of action exists under the FDCA and all proceedings to enforce or restrain violations of the statute must be brought by the FDA. Doc. 7351 at 11-12. The Court agrees with Defendants.[10]

"The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Indeed, § 337(a) expressly provides that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." Thus, "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist." *Leonard v.*

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[9] Specifically, Plaintiffs allege violations of 21 U.S.C. §§ 321, 331, 352, and 21 C.F.R. §§ 1.21, 801, 803, 807, 820. Doc. 364 ¶ 231(a)-(j).

[10] The Court reached the same conclusion in the Booker case. *See* Doc. 8874 at 14-18.

Medtronic, Inc., No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011) (citation omitted).

Plaintiffs assert no violation of a Georgia ordinance, regulation, or statute in support of their negligence per se claim. Thus, "as in *Buckman*, [Plaintiffs'] negligence per se claim (or, more appropriately characterized, [their] negligence claim based solely on violations of the FDA-Imposed Requirements or other FDA regulations) is impliedly preempted by the FDCA." *Grant v. Corin Grp. PLC*, No. 3:15-CV-169-CAB-BLM, 2016 WL 4447523, at *4 (S.D. Cal. Jan. 15, 2016); *see Buckman*, 531 U.S. at 353 (state law claim that a defendant violated the FDCA by making false statements to the FDA impliedly preempted by § 337(a) because the claim "exist[ed] solely by virtue" of the FDCA); *Leonard*, 2011 WL 3652311, at *8 (finding negligence per se claim preempted by § 337(a) where it "would not exist prior to the enactment of the FDCA misbranding and adulteration laws because the claim only alleges violation of that law").

Plaintiffs assert that *Leonard* is inapposite because, unlike Bard IVC filters, the medical device at issue in *Leonard* had been approved by the FDA through the rigorous premarket approval process. Doc. 7943 at 18. But this was not the basis for *Leonard*'s implied preemption finding. *Leonard* found implied preemption because "all proceedings to enforce or restrain violations of the FDCA 'shall be by and in the name of the United States.'" 2011 WL 3652311, at *7 (quoting § 337(a)). Moreover, preemption under § 337(a) is not limited to devices approved through the premarket approval process. The device at issue in *Buckman* – like the Eclipse filter in this case – was cleared for market under 510(k) review. 531 U.S. at 346-47.

Plaintiffs note that Georgia common law and § 51-1-6 recognize that laws which do not create a private right of action may nonetheless support a claim for damages. Doc. 7943 at 18-19 (citing *Amick v. BM & KM, Inc.*, 275 F. Supp. 2d 1378, 1282-83 (N.D. Ga. 2003) (finding that "the defendants breached the legal duties imposed by [Georgia code] sections 30-4-2 and 43-21-3 when they prohibited Amick and his service dog from staying at their hotel")). While it is true that courts generally have allowed a

negligence per se claim based on violation of a statute that does not expressly provide for a private right of action, "the plain language of § 337(a) and the *Buckman* decision indicate that, where the FDCA is concerned, such claim fails." *Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014).

The Court will grant summary judgment on Plaintiffs' negligence per se claim because allowing the claim to go forward would authorize an impermissible action to enforce provisions of the FDCA and its implementing regulations. *See Leonard*, 2011 WL 3652311, at *7-8; *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) (negligence per se claim preempted where it was based on allegations that the defendant violated the FDCA by selling a misbranded and adulterated product); *Connelly v. St. Jude Med., Inc.*, No. 5:17-cv-02005-EJD, 2017 WL 3619612, at *5 (N.D. Cal. Aug. 23, 2017) (negligence per se claim preempted where it was "based entirely on violations of the FDCA and its implementing regulations"); *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (finding fraud on the FDA claim preempted where the plaintiff was not suing under state law for conduct that happens to violate the FDCA, but instead is suing solely "*because* the conduct violates the FDCA.").

VII. Punitive Damages.

Under Georgia law, punitive damages may be awarded only where the defendant's actions "showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1(b). Defendants contend that punitive damages are not warranted because there is no evidence Bard acted with the requisite state of mind, and Bard otherwise complied with all applicable FDA regulations in bringing its filters to market. Doc. 7351 at 12-13. "Compliance with federal regulations, however, is not sufficient to automatically preclude an award of punitive damages." *Cason*, 2015 WL 9913809, at *6. This is particularly true where, as in this case, the device at issue was cleared by the FDA under 510(k) review which focuses primarily on equivalence with other products, not safety. *Cisson*, 2013 WL 5700513, at *12.

Plaintiffs claim that Bard's actions show a conscious indifference to the dangerous consequences posed by the Eclipse and its predecessor filters. Doc. 7943 at 19-23. Plaintiffs argue that a jury reasonably could award punitive damages because there is evidence that Bard knew that its retrievable filters were less safe than the SNF and were failing at higher rates than competitor devices, and yet never identified the root cause of the failures, provided adequate warnings, or recalled or suspended sales of Bard filters. *Id.* at 20-23. The Court previously found that Plaintiffs have presented evidence that, if believed by a jury, would be sufficient to support a finding that Bard knew the G2 filter was failing at significantly higher rates than other IVC filters, but did nothing to correct the problem or to warn doctors of the increased risk. Doc. 8874 at 20. Plaintiffs claim that the Eclipse is just a rebranded G2 or G2X filter, citing an internal Bard document explaining that the filter's name was changed to "break with the baggage associated with the previous versions despite the fact that the new iteration was the same as G2X in every way but one." Doc. 7943 at 22 (citing Doc. 7950 ¶ 102, Ex. 99).[11]

Defendants counter that the design change made to the Eclipse – electropolishing – was intended to improve fracture resistance and precludes a finding that Bard did "nothing" to address the issue of fracture. Doc. 8391 at 15-16. But Plaintiffs claim that Bard consciously chose not employ other known safety features in the Eclipse such as penetration limiters and caudal anchors to reduce the risk of perforation, tilt, and migration. Doc. 7943 at 22. Plaintiffs' expert on the design of Bard filters opines that filter failure modes can work synergistically, and that fractures are more likely to occur when a filter tilts, migrates, or perforates the IVC wall. Docs. 7807-1 at 21, 7319-1 at 37-38. Plaintiffs contend that the Eclipse suffered from the same design defects and caused the same type of injuries as its predecessors, and that rather than recalling the product from the market, making substantive design changes to improve patient safety, or warning physicians about the dangers, Bard simply renamed the device and continued

[11] The only modification to the G2X from the G2 was the addition of a snare hook to improve retrievability. The filters otherwise are the same.

selling it. Doc. 7943 at 22. Plaintiffs claim that the Eclipse was used as a stop-gap device so that Bard could maintain market share and profits while it engaged in a complete redesign of the filter. *Id.* at 22, 24-25.

Defendants vigorously dispute this view of the evidence, and claim that Bard could not have brought its subsequent generation filters to market by the time Mrs. Jones received an Eclipse filter. But if a jury were to believe Plaintiffs' version of events, it reasonably could "conclude that Bard acted with an entire want of care such that Bard was consciously indifferent to the consequences of its actions." *Cisson*, 2013 WL 5700513, at *14.

Defendants contend that incidents involving the Recovery and G2 line of filters are irrelevant because Plaintiffs cannot show a "substantial similarity" between those devices and the Eclipse. Doc. 8574 at 14-16. "To show substantial similarity, the plaintiff must come forward with evidence that the other 'incidents share a common design, common defect, and common causation with the alleged design defect at issue.'" *Chrysler Grp., LLC v. Walden*, 792 S.E.2d 754, 740 (Ga. Ct. App. 2016) (quoting *Colp v. Ford Motor Co.*, 630 S.E.2d 886, 889 (Ga. 2006)). Plaintiffs have met this burden.

It is undisputed that the Recovery filter was the predicate device for the G2, and Plaintiffs have presented evidence that the two devices share common design defects that have caused similar complications. *See* Docs. 8874 at 21, 10258 at 2-3. Plaintiffs also have presented evidence that the Eclipse is the same as the G2 line of filters with only one modification (electropolishing). Doc. 7950 ¶¶ 96, 101-102. Although the Eclipse may not be identical to the Recovery and G2, Plaintiffs have shown a "substantial similarity" between the filters.

IT IS ORDERED:

1. The following claims are **dismissed** based on Plaintiffs' withdrawal of the claims before Defendants moved for summary judgment: manufacturing defect (Counts I and V), negligent failure to recall or retrofit (Count VI), and breach of warranty (Counts X and XI).

2. Defendants' motion for partial summary judgment (Doc. 7351) is **granted in part and denied in part**. The motion is granted with respect to Plaintiffs' claims for misrepresentation (Counts VIII and XII), negligence per se (Count IX), and consumer fraud and unfair trade practices (Count XIV). The motion is denied with respect to the claims for failure to warn (Counts II and VII) and punitive damages. These claims, along with the claims for design defect (Counts III and IV), fraudulent concealment (Count XIII), and loss of consortium (Count XV), remain for trial.

3. A final pretrial conference is set for **May 4, 2018 at 10:00 a.m.** Doc. 10324. The trial is set to begin on **May 15, 2018 at 9:00 a.m**. Doc. 8144.

Dated this 12th day of March, 2018.

David G. Campbell
United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC
Doris Jones and Alfred Jones, Sr., Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00782-PHX-DGC **ORDER**

The Jones trial is set to begin on **May 15, 2018 at 9:00 a.m.** A final pretrial conference will be held on **May 4, 2018 at 10:00 a.m.** In preparation for trial, the Court enters the following orders:

1. The attorneys who will be responsible for the trial of the case shall attend the final pretrial conference.

2. The parties jointly shall prepare a proposed final pretrial order and shall lodge it with the Court no later than **4:00 p.m.** on **April 27, 2018**. Preparation and lodging of the proposed final pretrial order in accordance with the requirements of this order shall be deemed to satisfy the disclosure requirements of Rule 26(a)(3) of the Federal Rules of Civil Procedure. The parties shall submit a copy of the proposed final

pretrial order to the Court in Word format to Nancy_Outley@azd.uscourts.gov.

3. The proposed final pretrial order shall include the information prescribed in the Joint Proposed Final Pretrial Order form found at www.azd.uscourts.gov under: (1) Judges' Information, (2) Orders, Forms and Procedures, and (3) David G. Campbell. Information shall not be set forth in the form of a question, but shall be presented in concise narrative statements. With respect to jury instructions and the verdict form, the Court intends to use the preliminary and final jury instructions and the verdict form from the Booker trial. The parties need not follow the jury instruction form found at www.azd.uscourts.gov, but instead should simply submit their stipulated and proposed changes to the Booker instructions and verdict form. With respect to voir dire, the Court intends to ask the voir dire questions from the Booker trial. The parties should submit only stipulated and proposed changes to the Booker voir dire questions.

4. The Court will not allow the parties to offer any exhibit, witness, or other evidence that was not disclosed in accordance with the provisions of this order and the Federal Rules of Civil Procedure and listed in the proposed final pretrial order, except to prevent manifest injustice. Fed. R. Civ. P. 16(e). Objections to witnesses and documents should also be listed.

5. Plaintiffs shall have the burden of initiating communications concerning the proposed final pretrial order.

6. The parties shall (a) number and mark exhibits in accordance with the Exhibit Marking Instructions at www.azd.uscourts.gov under Judges and Courtrooms and Orders, Forms and Procedures (such numbers shall correspond to exhibits numbers listed in the proposed final pretrial order); (b) meet in person and exchange marked copies of all exhibits to be used at trial no later than **14 days** before the submission deadline for the proposed final pretrial order; and (c) eliminate any duplicate exhibits while meeting to exchange exhibits.

7. The parties shall file and serve all motions in limine no later than **April 18, 2018**. Responses to motions in limine shall be filed on or before

April 25, 2018. Each motion in limine shall state with precision the evidence that is the subject of the motion. The motions and responses must be concise and shall not exceed three (3) pages in length. No replies shall be filed. Counsel shall be prepared to argue the merits of such motions at the final pretrial conference.

8. The Court will hold a hearing on **April 13, 2018 at 10:00 a.m.**, to discuss issues decided in connection with the Booker trial that a party believes should be reconsidered for the Jones trial. The parties shall file 5-page memoranda identifying the issues they wish to be reconsidered, and summarizing their reasons, by **5:00 p.m.** Phoenix time on **April 10, 2018**. The memoranda should identify the docket numbers for briefs and orders that previously addressed the issues.

9. The parties shall provide deposition designations for the Court's ruling by **4:00 p.m. on April 20, 2018.**

10. In order to facilitate the creation of an accurate record, the parties shall file a "Notice to Court Reporter" **on or before May 8, 2018** containing the following information that may be used at trial:

(a) Proper names, including those of witnesses.

(b) Acronyms.

(c) Geographic locations.

(d) Technical (including medical) terms, names or jargon.

(e) Case names and citations.

(f) Pronunciation of unusual or difficult words or names.

11. Trial will be held on **May 15-18, 22-25, 29-31, and June 1, 2018**. On the basis of time used during the Booker trial, the fact that the Court believes the parties could have been more efficient, and the fact that Plaintiffs have the burden of proof, the Court will allocate **28 hours** to Plaintiffs and **27 hours** to Defendants.

12. The parties have stipulated to bifurcating the Jones trial into two phases following the procedures set out in Georgia's statute on punitive damages, O.C.G.A. § 51-12-5.1(d)(2). The first phase will determine liability, compensatory damages, and

whether punitive damages should be awarded. If necessary, the second phase will determine the amount of punitive damages. *See* Doc. 10048. The parties are reminded that if a second phase is needed, any time devoted to this punitive damages portion of the trial will be counted against the hours allotted to each side in paragraph 11 above.

13. Jury selection and use of jury questionnaires will be as outlined in the order at Doc. 10324.

Dated this 30th day of March, 2018.

David G. Campbell
United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, Debra Mulkey, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. MDL 15-02641-PHX DGC No. CV-16-00853-PHX-DGC **ORDER**

The Mulkey trial is set to begin on **September 18, 2018 at 9:00 a.m.** A final pretrial conference will be held on **August 30, 2018 at 10:00 a.m.** In preparation for trial, the Court enters the following orders:

1. The attorneys who will be responsible for the trial of the case shall attend the final pretrial conference.

2. The parties jointly shall prepare a proposed final pretrial order and shall lodge it with the Court no later than **4:00 p.m.** on **August 17, 2018**. Preparation and lodging of the proposed final pretrial order in accordance with the requirements of this order shall be deemed to satisfy the disclosure requirements of Rule 26(a)(3) of the Federal Rules of Civil Procedure. The parties shall submit a copy of the proposed final pretrial order to the Court in Word format to Nancy_Outley@azd.uscourts.gov.

3. The proposed final pretrial order shall include the information prescribed in the Joint Proposed Final Pretrial Order form found at www.azd.uscourts.gov under: (1) Judges' Information, (2) Orders, Forms and Procedures, and (3) David G. Campbell. Information shall not be set forth in the form of a question, but shall be presented in concise narrative statements. With respect to jury instructions and the verdict form, the Court intends to use the preliminary and final jury instructions and the verdict form from the Booker trial. The parties need not follow the jury instruction form found at www.azd.uscourts.gov, but instead should simply submit their stipulated and proposed changes to the Booker instructions and verdict form. With respect to voir dire, the Court intends to ask the voir dire questions from the Booker trial. The parties should submit only stipulated and proposed changes to the Booker voir dire questions.

4. The Court will not allow the parties to offer any exhibit, witness, or other evidence that was not disclosed in accordance with the provisions of this order and the Federal Rules of Civil Procedure and listed in the proposed final pretrial order, except to prevent manifest injustice. Fed. R. Civ. P. 16(e). Objections to witnesses and documents should also be listed.

5. Plaintiffs shall have the burden of initiating communications concerning the proposed final pretrial order.

6. The parties shall (a) number and mark exhibits in accordance with the Exhibit Marking Instructions at www.azd.uscourts.gov under Judges and Courtrooms and Orders, Forms and Procedures (such numbers shall correspond to exhibits numbers listed in the proposed final pretrial order); (b) meet in person and exchange marked copies of all exhibits to be used at trial no later than **14 days** before the submission deadline for the proposed final pretrial order; and (c) eliminate any duplicate exhibits while meeting to exchange exhibits.

7. The parties shall file and serve all motions in limine no later than **July 27, 2018**. Responses to motions in limine shall be filed on or before **August 10, 2018.** Each motion in limine shall state with precision the evidence that is

the subject of the motion. The motions and responses must be concise and shall not exceed three (3) pages in length. No replies shall be filed. Counsel shall be prepared to argue the merits of such motions at the final pretrial conference.

8. The parties shall provide deposition designations for the Court's ruling by **4:00 p.m. on August 15, 2018.**

10. In order to facilitate the creation of an accurate record, the parties shall file a "Notice to Court Reporter" **on or before August 17, 2018** containing the following information that may be used at trial:

(a) Proper names, including those of witnesses.

(b) Acronyms.

(c) Geographic locations.

(d) Technical (including medical) terms, names or jargon.

(e) Case names and citations.

(f) Pronunciation of unusual or difficult words or names.

11. Trial will be held on **September 18-21, 24-28, and October 1-5, 2018**. The Court will allocate **33 hours** to Plaintiffs and **30 hours** to Defendants.

12. Jury selection and use of jury questionnaires will be as outlined in the order at Doc. 11320.

Dated this 1st day of June, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **CASE MANAGEMENT ORDER NO. 34**

Following the close of the second bellwether trial, the Court conferred with the parties regarding scheduling matters. The parties agreed on the Mulkey case as the next bellwether trial for September 2018. The Court directed the parties to file memoranda addressing other bellwether trials and cases in this MDL. Doc. 11320. Having reviewed the memoranda, the Court enters the following order:

I. Next Three Bellwether Trials: Kruse, Hyde, and Mulkey.

During a recent telephonic conference, counsel for Ms. Mulkey expressed concern about her availability for trial in September due to certain health issues. Doc. 11549. Counsel thereafter provided an update on her condition which leaves her availability for trial uncertain. Doc. 11639. Defendants have no objection to a different case for the next bellwether, and propose Kruse in lieu of Mulkey. Doc. 11640. Plaintiffs propose Hyde as the next bellwether. Doc. 11553.

Having considered the parties' positions, the Court concludes that the order of the next three bellwether trials should be as follows: Kruse, Hyde, and Mulkey. Trial in the Kruse bellwether will begin in **September 2018** as set forth below. Trial in the Hyde

bellwether will be held on **November 5-9**, **12-16**, and **19-20**. Trial in the Mulkey bellwether will be held in **February 2019**. The Court will set the specific trial dates by separate order.

II. Kruse Trial.

The dates and deadlines set forth in Case Management Order No. 33 for the Mulkey trial will apply to the Kruse bellwether as follows (see Doc. 11320 for further details):

A. Jury Questionnaire and Jury Selection for Kruse Trial.

1. By **July 5, 2018**, the parties shall provide the Court with proposed changes to the questionnaire used in the Jones bellwether trial. The Court will consider these proposals in finalizing the questionnaire for the Kruse trial.

2. The Clerk shall mail the questionnaire to 200 jurors no later than **July 13, 2018.** The questionnaire will instruct the prospective jurors to return it to the Court no later than **August 10, 2018**.

3. A thumb drive will be prepared for counsel (one for each side) containing copies of the questionnaires and will be available for pickup at the jury office on **August 17, 2018.** The thumb drive and any paper copies made by counsel must be returned to the Court by counsel on the day of jury selection.

4. On **August 24, 2018**, the Court will provide the parties with a list of prospective jurors the Court proposes to excuse for hardship on the basis of their responses to the first question in the questionnaire.

5. The Court will hold a final pretrial conference in the Kruse case on **August 30, 2018 at 10:00 a.m.** and will address with the parties juror excusals for hardship and challenges for cause. *See* Doc. 11320 at 2, ¶ 2(e).

6. On **September 18, 2018, at 9:00 a.m.,** 50 prospective jurors will be called to Court to appear for voir dire. Following voir dire, the Court will hear and rule on challenges for cause. The Court will seat 9 jurors. Each side will have 3 pre-emptory strikes. *See* Doc. 11320 at 2, ¶ 2(f).

B. Kruse Motion for Summary Judgment.

The Court will rule on the Kruse summary judgment motion as soon as possible.

C. Motions in Limine.

Motions in limine, limited to three pages each, shall be filed by **July 27, 2018**. Responses to motions in limine, limited to three pages each, shall be filed by **August 10, 2018**. No replies shall be filed.

Defendants may re-urge their motion in limine regarding Recovery death evidence (Doc. 9862) pursuant to the schedule set forth above. Memoranda on this issue may be up to 5 pages long. The parties shall not repeat arguments previously made. The issue was fully briefed for the Booker trial, and the Court has addressed Recovery death evidence in several orders. Docs. 10258, 10819, 10920, 11041.[1]

D. Deposition Designations.

The parties shall provide deposition designations by **August 15, 2018**.

E. Proposed Final Pretrial Order.

The proposed final pretrial order for the Kruse bellwether shall be submitted by **August 17, 2018**. The Court will enter a separate order governing the materials that should be submitted with the proposed final pretrial order.

F. Trial days.

Trial in the Kruse bellwether will be held on **September 18-21** and **24-28**, and **October 1-5**. Plaintiff will be allotted **33 hours** of trial time and Defendants will be allotted **30 hours** of trial time. This schedule should allow the case to get to the jury by the morning of October 4, 2018.

G. Dr. Kandarpa.

Kruse may use Dr. Kandarpa as a witness at trial. *See* Doc. 11320 at 4, ¶ 9.

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[1] The Court stated that it would propose a new schedule for Plaintiffs' *Cisson* motion if the Mulkey case were to be replaced. Doc. 11549. Plaintiffs have made clear, however, that they do not intend to re-urge the motion regardless of which case is chosen for the third bellwether. Doc. 11639 at 3.

III. The Sixth Bellwether: Tinlin.

Defendants propose the King case for the sixth bellwether, and Plaintiffs propose Tinlin. Docs. 11550, 11553. The five cases already selected for bellwether trials consist of three G2 cases (Booker, Kruse, and Hyde) and two Eclipse cases (Jones and Mulkey). The Court agrees with Plaintiffs that it is important to have a Recovery case as one of the six bellwether trials. Doc. 11553 at 2-3. The Tinlin case is the only potential bellwether that involves a Recovery filter. The Court previously found Tinlin to be a strong candidate for a bellwether, but expressed concern that she may not be able to endure the rigors of an out-of-state trial due to her illness. Doc. 5770 at 1-2. Plaintiffs, however, have confirmed that Tinlin is willing and able to travel to Arizona for trial. Doc. 11553 at 3.

For reasons stated on the record at the ninth case management conference, the Court does not view King as a helpful bellwether case. Doc. 5770 at 2. Defendants do not address those concerns in their memorandum. Moreover, King involves a G2 like three of the other bellwether cases. Defendants assert that the King case is representative of the MDL inventory as a whole because it involves perforation and an unsuccessful retrieval attempt. Doc. 1550 at 2. But even if this were true, the Court finds that it is more important for the sixth bellwether to be a Recovery case.[2]

Trial in the Tinlin bellwether will be held in **May 2019**. The Court will determine the specific trial dates after the Kruse trial.

IV. Disposition of the SNF Cases.

The nearly 100 Simon Nitinol Filter ("SNF") cases should not be part of this MDL. The SNF is not part of the master complaint, which is limited to Bard retrievable filters. Doc. 364. The SNF cases have been filed by more than 20 different law firms. Defendants do not oppose the request by Plaintiffs' counsel to have 30 days to obtain

[2] Given the selection of Tinlin for the sixth bellwether, the Court need not consider Plaintiffs' alternative choice, DeWitt. Neither side proposes Nelson, Peterson, or Mixson as the final bellwether case.

responses from the firms representing the SNF plaintiffs as to what action should be taken in those cases. Doc. 11550 at 4. Plaintiffs shall file a notice regarding the status of the SNF cases by **July 16, 2018**.

V. Remand of the "Mature" Cases.

More than two years ago, the parties estimated that the 10 mature cases would be "ripe for remand in 4-6 months." Doc. 914 at 2. Since that time, common fact discovery and expert disclosures in this MDL have been completed, and the Court has ruled on *Daubert* motions and Defendants' summary judgment motion based on preemption. The Court concludes that it is time to remand the mature cases to their home districts. The Court will look into the proper procedure for remand and invite briefing if necessary.

Dated this 28th day of June, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **CASE MANAGEMENT ORDER NO. 35**

As set forth in Case Management Order No. 34, the bellwether cases are scheduled for trial as follows: Kruse (September 2018), Hyde (November 2018), Mulkey (February 2019), and Tinlin (May 2019). Doc. 11659 at 1-4. The Court has determined that it must grant summary judgment in favor of Defendants on the claims asserted by Plaintiff Kruse. *See* Doc. 11839. The Court held a conference call with the parties today to discuss scheduling issues and whether the Hyde case could be moved to the September bellwether slot in lieu of the Kruse case. On the basis of the conference, the Court enters the following order:

I. September 2018 Bellwether: Hyde.

The parties agreed that in lieu of Kruse, and with certain scheduling modifications, the Hyde case can be tried in September. The dates and deadlines set forth in Case Management Order No. 34 (Doc. 11659) are modified in part as follows for the Hyde trial:

A. Jury Questionnaire and Selection.

1. By **July 18, 2018**, the parties shall provide the Court with proposed

changes to the jury questionnaire used in the Jones trial. The Court will consider these proposals in finalizing the questionnaire for the Hyde trial.

2. The Clerk shall mail the questionnaire to 200 jurors no later than **July 20, 2018.** The questionnaire will instruct the prospective jurors to return it to the Court no later than **August 17, 2018**.

3. A thumb drive will be prepared for counsel (one for each side) containing copies of the questionnaires and will be available for pickup at the jury office on **August 24, 2018.** The thumb drive and any paper copies made by counsel must be returned to the Court by counsel on the day of jury selection.

4. On **August 30, 2018**, the Court will provide the parties with a list of prospective jurors the Court proposes to excuse for hardship on the basis of their responses to the first question in the questionnaire.

5. The Court will hold a final pretrial conference in the Hyde case on **September 6, 2018 at 10:00 a.m.** and will address with the parties juror excusals for hardship and challenges for cause. *See* Doc. 11320 at 2, ¶ 2(e).

6. On **September 18, 2018, at 9:00 a.m.**, 50 prospective jurors will be called to Court to appear for voir dire. Following voir dire, the Court will hear and rule on challenges for cause. The Court will seat 9 jurors. Each side will have 3 pre-emptory strikes. *See* Doc. 11320 at 2, ¶ 2(f).

B. Motion for Summary Judgment.

The Court will rule on the choice-of-law issue raised in the Hyde summary judgment motion (Doc. 7359) by **July 25, 2017**. The Court will endeavor to rule on the remaining summary judgment issues in Hyde as soon as possible.

C. Motions in Limine.

Motions in limine, limited to three pages each, shall be filed by **August 10, 2018**. Responses to motions in limine, limited to three pages each, shall be filed by **August 24, 2018**. No replies shall be filed.

Defendants may, if they so choose, re-urge their motion in limine regarding

Recovery death evidence (Doc. 9862) pursuant to the schedule set forth above. Memoranda on this issue may be up to 5 pages long. The parties shall not repeat arguments previously made. The issue was fully briefed for the Booker trial, and the Court has addressed Recovery death evidence in several orders. Docs. 10258, 10819, 10920, 11041.[1]

D. Deposition Designations.

The parties shall provide deposition designations by **August 22, 2018**.

E. Proposed Final Pretrial Order.

The proposed final pretrial order for the Hyde bellwether shall be submitted by **4:00 p.m.** on **August 24, 2018**. The Court will enter a separate order governing the materials that should be submitted with the proposed final pretrial order.

F. Trial Days.

The trial dates for the Hyde bellwether will remain the same as those set for Kruse: **September 18-21** and **24-28**, and **October 1-5**. Plaintiff will be allotted **33 hours** of trial time and Defendants will be allotted **30 hours** of trial time. This schedule should allow the case to get to the jury by the morning of October 4, 2018. *See* Docs. 11320 at 3-4, 11659 at 3.

G. Dr. Kandarpa.

Hyde may use Dr. Kandarpa as a witness at trial. *See* Doc. 11320 at 4, ¶ 9.

II. November 2018 Bellwether.

Trial in this bellwether slot will be held on **November 5-9**, **13-16**, **19-20**, and **26-28**. The parties should note that these dates have been modified (*see* Doc. 11659 at 2) to allow for 14 trial days and account for the federal holiday on November 12 (Veterans Day). The Plaintiff for the fourth bellwether (Mulkey or Tinlin) will be determined after

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[1] The Court previously stated that it would propose a new schedule for Plaintiffs' *Cisson* motion if a new case were selected for the September 2018 bellwether slot. Doc. 11549. Plaintiffs have made clear, however, that they do not intend to re-urge the motion regardless of which case is chosen for the third bellwether. Doc. 11639 at 3.

the parties file memoranda concerning Mulkey's health condition and the feasibility of Tinlin's case being tried in November.

III. February 2019 Bellwether.

Trial in this bellwether slot will be held on **February 11-15**, **19-22**, **25-28**, and **March 1, 2019**.

IV. May 2019 Bellwether.

The Court will determine whether a sixth bellwether trial should be held, and the specific Plaintiff and dates for such bellwether, after the Hyde trial.

Dated this 13th day of July, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC
Lisa Hyde and Mark E. Hyde, a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00893-PHX-DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters. The MDL Plaintiffs received implants of Bard IVC filters and claim that they are defective and have caused serious injury or death.

One of the MDL cases is brought by Plaintiffs Lisa and Mark Hyde. Mrs. Hyde received a Bard filter seven years ago. Her case has been selected as one of several bellwether cases and is set for trial in September 2018. Defendants have filed a motion

for partial summary judgment. Doc. 7359. The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will grant the motion in part and deny it in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. An IVC filter is a device implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves multiple versions of Bard IVC filters – the Recovery, G2, G2X, Eclipse, Meridian, and Denali. They are spider-shaped devices that have multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with elastic hooks that attach to the IVC wall and curved arms to catch or break up blood clots. Each of these filters is a variation of its predecessor.

The MDL Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have higher risks of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs further allege that Bard failed to warn patients and physicians about these higher risks. Defendants dispute these allegations, contending that Bard filters are safe and effective, that their complication rates are low and comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters.

II. The Hyde Plaintiffs.

The following facts are not disputed for summary judgment purposes. Plaintiff Lisa Hyde has a history of deep vein thrombosis and pulmonary emboli. On February 25, 2011, she received a Bard G2X filter while living in Wisconsin.[1] Dr. David Henry

[1] The parties disagree on whether Mrs. Hyde's filter was a G2X or Eclipse. Defendants stated that Mrs. Hyde received a G2X filter when she was proposed as a bellwether plaintiff (Doc. 5652 at 6), but they now assert that the device likely was an Eclipse based on hospital sales records, copies of which have not been provided to the Court. Doc. 7359 at 2 n.2. Plaintiffs present medical records and physician testimony suggesting the filter was a G2X, but their cited documents are incomplete. Doc. 7952 at 1-2 n.1 (citing Doc. 7950 ¶¶ 150, 153, 162-63). The parties agree that the filter type has no bearing on this motion (*id.*; Doc. 7359 at 2 n.20), and, for ease of reference, this order will assume the filter was a G2X. By August 10, 2018, the parties shall confer and report to the Court on whether there is a means for determining the filter type prior to trial, or whether this will be an issue for the jury.

implanted the filter without incident. In May 2014, after Mrs. Hyde and her husband had moved to Nevada, a CT scan showed that the filter had tilted, perforated the IVC wall, and fractured, with one strut lodged in the right ventricle of her heart. The filter and fractured strut were removed in August 2014.

Mrs. Hyde and her husband assert various claims against Bard: failure to warn (Counts II and VII), design defects (Counts III and IV), failure to recall (Count VI), misrepresentation and concealment (Counts VIII, XII, and XIII), negligence per se (Count IX), breach of implied warranty (Count XI), fraudulent trade practices (Count XIV), loss of consortium (Count XV), and punitive damages. *See* Doc. 364 (master complaint); Doc. 1, Case No. CV-16-00893 (short-form complaint).[2]

Defendants seek summary judgment on the claims for strict liability design defect, failure to warn, failure to recall, misrepresentation and fraud, and breach of implied warranty. Doc. 7359 at 2-4. Plaintiffs concede that summary judgment is proper on the failure to recall and implied warranty claims. Doc. 7952 at 2 n.2. The Court will deny summary judgment on the strict liability design defect claim, but otherwise will grant Defendants' motion. Defendants do not seek summary judgment on claims for negligent design (Counts IV), negligence per se (Count IX), loss of consortium (Count XV), or punitive damages. These claims, plus strict liability design defect, remain in the case.

III. Choice of Law.

Because Wisconsin is the forum where venue would be proper absent this MDL, the parties agree that Wisconsin's conflict-of-law rules should be used to determine the governing law in this case. Docs. 7359 at 5, 7952 at 3; *see* Doc. 1 at 2, Case No. CV-16-00893 (identifying the Eastern District of Wisconsin as the forum court); *see Love v. Blue*

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[2] The master complaint is the operative pleading in this MDL. Doc. 364. It serves as a long-form complaint giving notice, pursuant to Rule 8, of the allegations that Plaintiffs assert generally. Plaintiff-specific allegations are contained in individual short-form complaints and fact sheets. Doc. 249 at 6. The master complaint asserts 17 claims and seeks both compensatory and punitive damages. Doc. 364 ¶¶ 166-349. The Hydes are not pursuing claims for manufacturing defect (Counts I and V), breach of express warranty (Count X), wrongful death (Count XVI), and survival (Count XVII). Doc. 7359 at 2 n.1; Doc. 1 at 4, Case No. CV-16-00893.

Cross & Blue Shield of Ga., Inc., 439 F. Supp. 2d 891, 892 (E.D. Wis. 2006) (federal courts "apply the choice-of-law rules of the forum state to determine the applicable substantive law"). Defendants argue that Wisconsin law applies. Doc. 7359 at 6. Plaintiffs argue that Nevada law applies. Doc. 7952 at 3.[3]

Wisconsin employs a two-step choice-of-law analysis. Step one considers whether "'the contacts of one state to the facts of the case are so obviously limited and minimal that application of that state's law constitutes officious intermeddling.'" *NCR Corp. v. Transp. Ins. Co.*, 823 N.W.2d 532, 535 (Wis. Ct. App. 2012) (quoting *Beloit Liquidating Trust v. Grade*, 677 N.W.2d 298, 307 (Wis. 2004)). If neither state's contacts are insignificant, step two considers several "choice-influencing" factors. *Id.* at 536 (citing *Drinkwater v. Am. Fam. Mut. Ins. Co.*, 714 N.W.2d 568, 576 (Wis. 2006); *Heath v. Zellmer*, 151 N.W.2d 664, 672 (Wis. 1967)).

A. Step One – State Contacts.

In evaluating the contacts with each state, the Court must consider the place of contracting, if any, the place of negotiation of any contract, the place of performance, the location of the subject matter, and the domicile, residence, nationality, place of incorporation, and place of business of the parties. *See NCR Corp.*, 823 N.W.2d at 535 (citing *Haines v. Mid-Century Ins. Co.*, 177 N.W.2d 328 (Wis. 1970)); Restatement (Second) of Conflicts § 188. Where tort claims are made, courts also consider the locations of the tortious conduct and the injury. *See id.* at 535-36 & n.2 (citing *Drinkwater*, 714 N.W.2d at 576; *Beloit*, 677 N.W.2d at 307; Restatement § 145).

In this case, the places of contracting, negotiation, and performance are not relevant because the parties never entered into a contract. Other factors are relevant. Plaintiffs were residents of Wisconsin when Mrs. Hyde received her Bard filter (Docs. 7950 ¶ 151, 7953 ¶¶ 1-2), her medical conditions leading to the filter implant occurred in Wisconsin (*id.*), and the filter was sold in Wisconsin and implanted by a

[3] The filter was removed in California, but neither side contends that California law applies.

Wisconsin doctor (Doc. 7953 ¶¶ 4, 17). On the other hand, Plaintiffs moved to Nevada after Mrs. Hyde received her filter, the filter's failure and resulting injuries were discovered in Nevada, and Plaintiffs still reside there. Doc. 7950 ¶ 156. Considering all of these facts, the Court finds that both Wisconsin and Nevada have significant contacts with this case.

"Because there is a weak presumption in favor of applying the forum law, the nonforum state's contacts must be clearly more significant for that state to prevail under this first step." *NCR Corp.*, 823 N.W.2d at 535 (citing *Drinkwater*, 714 N.W.2d at 576); *see State Farm Mut. Auto. Ins. Co. v. Gillette*, 641 N.W.2d 662, 676 (Wis. 2002); *In re Jafari*, 569 F.3d 644, 649 (7th Cir. 2009). Nevada's contacts with this case are not clearly more significant than Wisconsin's, but neither are they "so obviously limited and minimal" that application of Nevada law would constitute officious intermeddling. *Beloit*, 677 N.W.2d at 307; *see Drinkwater*, 714 N.W.2d at 576-77 (finding Iowa's contacts to be significant but not greater than Wisconsin's where the accident and injuries occurred in Wisconsin and the insurance contract was formed in Iowa); *Love*, 439 F. Supp. 2d at 892 (application of the foreign state's law "only constitutes 'officious intermeddling' if the other state is truly of remote connection to the issues in the case"). As a result, the Court must proceed to step two of the choice-of-law inquiry. *See In re Jafari*, 569 F.3d at 649 ("[I]f it is not clear that the nonforum contacts are of greater significance, then the court typically analyzes as a tie-breaker the five choice-influencing factors developed in *Heath*[.]").

Plaintiffs cite *NRC Corp.* and argue that great weight should be given to the location of the tortious conduct and the location of the injury. Doc. 7952 at 5. But the court in *NRC Corp.* did not find these two factors to be "qualitatively stronger" on their own; it found them stronger on the facts of the case before it because they were "the only factors that conclusively weigh[ed] in favor of either [state's] law[.]" 823 N.W.2d at 538. Here, there are several significant contacts with Nevada and Wisconsin. Moreover, Plaintiffs do not contend that the tortious conduct in this case occurred in Nevada.

Plaintiffs' reliance on *Drinkwater* fares no better. Doc. 7952 at 5. The accident and injury in that case occurred in Wisconsin, but the court nonetheless declined to resolve the choice-of-law issue at step one because, as here, the contacts with each state were significant. 714 N.W.2d at 577 ("Iowa's contacts are more than minimal and limited. We therefore turn to apply the five choice-influencing factors." (citation omitted)).

Plaintiffs claim that the district court in *Johnson v. Mylan Inc.*, 107 F. Supp. 3d 967 (E.D. Wis. 2015), applied the state-contacts analysis and determined that Wisconsin law should apply because the illness, treatment, and death occurred in that state. Doc. 7952 at 5. To the contrary, no choice-of-law analysis was needed in *Johnson* because the parties agreed that Wisconsin law applied. 107 F. Supp. 3d at 970. Moreover, the court made clear that "the law of the forum state governs a tort case unless it is clear that nonforum contacts are more significant." *Id.* (citing *Gillette*, 641 N.W.2d at 675-76); *see Schultz*, 2013 WL 4959007, at *4 (applying the law of Wisconsin where the tortious conduct occurred even though the decedent died in Florida and his widow lived there).

B. Step Two – Choice-Influencing Factors.

Step two considers five factors: (1) predictability of results, (2) maintenance of interstate and international order, (3) simplification of the judicial task, (4) advancement of the forum state's interests, and (5) application of the better rule of law. *See NCR Corp.*, 823 N.W.2d at 536 (citing *Drinkwater*, 714 N.W.2d at 576; *Heath*, 151 N.W.2d at 672). "The appropriate law, unless the above factors clearly displace it, is the law of the forum." *Sentry Ins. v. Novelty, Inc.*, No. 09-CV-355-SLC, 2009 WL 5087688, at *5 (W.D. Wis. Dec. 17, 2009).

1. Predictability of Results.

This factor concerns the parties' expectations as to the legal consequences of the conduct that led them to court. *See Drinkwater*, 714 N.W.2d at 577. Bard's interactions with the physician who implanted Mrs. Hyde's filter occurred in Wisconsin, Bard sold

the filter to a Wisconsin hospital, and the filter was implanted while Mrs. Hyde lived in Wisconsin. Doc. 7953 ¶¶ 1-2, 4-5, 17. It was thus reasonable for Bard to expect that Wisconsin law would apply to any product liability claims arising from the filter's use. *See Beloit*, 677 N.W.2d at 308 (corporations are "on notice that, if they choose to transact business in this state, they will be subject to Wisconsin law"); *Schultz v. Glidden Co.*, No. 08-C-919, 2013 WL 4959007, at *4 (E.D. Wis. Sept. 13, 2013) ("[Defendant] purposefully marketed and sold its products to a company doing business in Wisconsin, so the application of Wisconsin law could not have been unexpected."); *Brooks v. Gen. Cas. Co. of Wis.*, No. 06-C-0996, 2007 WL 4305577, at *4 (E.D. Wis. Dec. 7, 2007) ("[D]efendants, in the course of doing business in Wisconsin, had no reason to expect that the legal consequence of conduct undertaken there would be wrongful death damages that exceed the limitations set by Wisconsin law."). Conversely, the parties could not reasonably have expected Nevada law to apply to filter-related claims because Plaintiffs' move to Nevada for employment reasons was a "fortuitous happenstance, not a predictable result." *Schultz*, 2013 WL 4959007, at *4. This factor favors application of Wisconsin law.

2. Maintenance of Interstate Order.

This factor is a variation of the "officious intermeddling" test applied at step one. *See Extrusion Dies Indus., LLC v. Cloeren Inc.*, No. 08-CV-323-SLC, 2008 WL 4401219, at *4 (W.D. Wis. Sept. 24, 2008). It requires that "a jurisdiction which is minimally concerned defer to a jurisdiction that is substantially concerned." *Drinkwater*, 714 N.W.2d at 577; *see Heath*, 151 N.W.2d at 672. Here, as explained above, "both jurisdictions are more than minimally concerned." *Drinkwater*, 714 N.W.2d at 577; *see also Love*, 439 F. Supp. 2d at 895 (application of one state's law over another's would not upset interstate order where neither jurisdiction is minimally concerned nor is there an indication of forum shopping). This factor is neutral.

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3. Simplification of the Judicial Task.

This factor is also neutral. A federal court managing an MDL proceeding, like courts sitting in diversity, "can apply one state's law as easily as another's." *Extrusion*, 2008 WL 4401219, at *4; *see also Love*, 439 F. Supp. 2d at 895.

4. Advancement of the Forum State's Interests.

Where "application of forum law will advance the governmental interest of the forum state, this fact becomes a major, though not in itself a determining, factor in the ultimate choice of law." *Heath*, 151 N.W.2d at 663. Plaintiffs assert that Wisconsin and Nevada have an equal interest in regulating a corporation that has sold a defective product. Doc. 7952 at 7. But this factor focuses on the *forum state's interests*, not the interests of the foreign jurisdiction. Wisconsin has a strong interest in having its laws applied to corporations transacting business within the state. *See Beloit*, 677 N.W.2d at 308. This factor favors application of Wisconsin law.

5. Application of the Better Rule of Law.

This factor asks which state provides "the 'better law' under the circumstances." *Heath*, 151 N.W.2d at 673. Plaintiffs assert that the interests of justice favor applying the law of the state where Mrs. Hyde was injured and resides, but do not explain why Nevada provides the better rule of law. Doc. 7952 at 7. Defendants contend that Wisconsin's adoption of a product liability statute in 2011 indicates that the state considers its legal standards the better rule of law, but do not explain why the views of the state legislature control. Doc. 7359 at 9.

The Court has difficulty with the task of identifying the "better" law. As one court has noted: "Better for whom? Better in what way?" *Extrusion*, 2008 WL 4401219, at *4. Furthermore, "when the question undoubtedly involves compromises between numerous interested groups, such judgments are best preserved for elected legislators." *Love*, 439 F. Supp. 2d at 897. The Court need not wrestle long with this difficulty, however, because it appears this factor seeks only to identify laws that are obsolete. *See Heath*, 151 N.W.2d at 673 (asking whether law is "outmoded, an unrepealed remnant of a

bygone age, [or] 'a drag on the coattails of civilization'" (citation omitted)). Neither Wisconsin's nor Nevada's product liability law can accurately be characterized as "obsolete or senseless[.]" *Id.* The Court therefore concludes that the fifth factor is neutral. *See Gillette*, 641 N.W.2d at 678 (finding this factor neutral where it could not be said that the foreign state's law "is anachronistic or fails to reflect modern trends"); *Schultz*, 2013 WL 4959007, at *4 (Florida did not provide the better rule of law where Wisconsin's rule was not "anachronistic, or the vestige of a 'creed outworn'" (citation omitted)); *Clorox Co. v. S.C. Johnson & Son, Inc.*, 627 F. Supp. 2d 954, 968 (E.D. Wis. 2009) ("The court has no basis on which to conclude that California law is somehow anachronistic on this point of law. Therefore, the court finds that the fifth factor does not favor the application of either Wisconsin or California law.").

C. Conclusion.

The contacts with each state are more than minimal, precluding a decision at step one; none of the step-two factors favors application of Nevada law; and two of the factors favor application of Wisconsin law. The Court therefore will apply Wisconsin law in this case. *See Drinkwater*, 714 N.W.2d at 579-80 (applying Wisconsin law where "[a]ll of the factors either point to the application of Wisconsin law or are neutral"); *Brooks*, 2007 WL 4305577, at *6 (applying Wisconsin law where none of the factors favored application of the foreign state's law).

IV. Summary Judgment.

A party seeking summary judgment "bears the initial responsibility of informing the court of the basis for its motion and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes over facts that might affect the outcome of the suit will preclude summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving

party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence must be viewed in the light most favorable to the nonmoving party, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), and all justifiable inferences are drawn in that party's favor because "[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions," *Anderson*, 477 U.S. at 255.

A. Strict Liability Claims (Counts II and III).

Plaintiffs assert strict liability failure to warn and design defect claims. Doc. 1 at 3, Case No. CV-16-00893. Under Wisconsin's product liability statute, Wis. Stat. § 895.047, a manufacturer is liable where the plaintiff shows the product is "defective in design, or is defective because of inadequate instructions or warnings." § 895.047(1)(a). A product is defective if its foreseeable risks of harm could have been reduced or avoided by the adoption of a reasonable alternative design or warning, and the omission of such alternative renders the product not reasonably safe. *Id.*; *see Lexington Ins. Co. v. Whesco Grp., Inc.*, No. 11-CV-598-BBC, 2013 WL 4454959, at *8 (W.D. Wis. Aug. 16, 2013).

The statute provides several defenses. Wis. Stat. § 895.047(3)(a)-(e). Defendants assert three in this motion. Defendants first contend that the G2X filter is presumed to be non-defective under § 895.047(3)(b) because the device was cleared by the Food and Drug Administration ("FDA"). Doc. 7359 at 10-13. Defendants further contend that the strict liability claims are barred under § 895.047(3)(d) because the risks associated with IVC filters are well known and inherent characteristics of the product. *Id.* Finally, Defendants claim that Plaintiffs provide no alternative design or warning as required by § 895.047(1)(a). *Id.*

1. Section 895.047(3)(b): Compliance with Government Standards.

Section 895.047(3)(b) creates a rebuttable presumption that a product is not defective if, at the time of sale, it complied with "relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency[.]" The design of the G2X filter and the warnings provided with the device are presumed to be non-

defective, Defendants contend, because Bard complied with the FDA's 510(k) process. Docs. 7359 at 12. Defendants claim that Plaintiffs cannot rebut the presumption. *Id.*

Cases have held that § 895.047(3)(b) creates no rebuttable presumption for medical devices cleared under 510(k) review because that review does not concern the safety of the product. *See Hall v. Boston Sci. Corp.*, No. 2:12-CV-08186, 2015 WL 874888, at *2 (S.D. W. Va. Feb. 27, 2015) ("510(k) is not a 'relevant standard' here. Section 895.047 concerns whether a defect rendered the product 'unreasonably dangerous,' § 895.047(1), and, as the Supreme Court has held, 510(k) compliance does not go to the safety of a product."); *Williams v. Boston Sci. Corp.*, No. 2:12-CV-02052, 2016 WL 1448860, at *3 (S.D. W. Va. Apr. 12, 2016) (same). Defendants argue that these cases were wrongly decided. Doc. 8392 at 5. The Court does not agree.

Under Wisconsin's statute, a product is defective only if it is "not reasonably safe." Wis. Stat. § 895.047(1)(a). The 510(k) clearance process, however, "is focused on *equivalence*, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (emphasis in original). The FDA does not approve the product or make a determination that the device is safe and effective; it finds only that the product is substantially equivalent to a predicate device. *See* 21 U.S.C. § 360c(f)(1)(A); 21 C.F.R § 807.97 (510(k) clearance "does not in any way denote official approval of the device"); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) (citing *Lohr* and noting that "products entering the market through 510(k) may be marketed only so long as they remain substantial equivalents of the relevant [predicate] devices as a qualification for an exemption [from federal safety review] rather than a requirement"); *Hovey v. Cook Inc.*, 97 F. Supp. 3d 836, 845 (S.D. W. Va. Apr. 1, 2015) (510(k) review "is predominantly relative, and the FDA does not engage in an independent investigation of the medical device's safety and effectiveness").

Because the 510(k) clearance process focuses on equivalence, not safety, the presumption of non-defectiveness afforded by § 895.047(3)(b) is not applicable. Given

this ruling, the Court need not determine whether Plaintiffs' have presented sufficient evidence to rebut the presumption. *See* Doc. 7952 at 9.[4]

2. Section 895.047(3)(d): Known and Inherent Characteristics.

Section 895.047(3)(d) requires dismissal of strict liability claims where the harm was caused by "an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product." Defendants contend that the complications associated with IVC filters – migration, tilt, perforation, and fracture – are inherent characteristics of the device and are well known in the medical community. Doc. 7359 at 10-13. Defendants rely on guidelines published by the Society of Interventional Radiology, a 2010 FDA safety alert, and testimony from the implanting physician and one of Plaintiffs' experts to show that the types of complications experienced by Mrs. Hyde were widely known before the implant procedure. *Id.* at 10-11.

Plaintiffs acknowledge that IVC filters experience adverse events, but contend that Bard's own analysis shows that the G2-line of filters experienced adverse events at rates higher than other IVC filters. Doc. 7952 at 10. Plaintiffs argue that these increased risks were not known and inherent characteristics of the product. *Id.* at 11.

Defendants challenge Plaintiffs' rate calculations as inaccurate, but this dispute simply creates a triable issue of fact. Doc. 8392 at 6-7. Defendants have not shown that they are entitled to summary judgment based on the defense provided by § 895.047(3)(d).

3. Section 895.047(1)(a): Alternative Design and Warning.

Section 895.047(1)(a) requires the plaintiff to show that the harm posed by the product could have been reduced or avoided with a reasonable alternative design or warning. Defendants claim that Plaintiffs provide no such alternatives. Doc. 7359 at 11-13. The Court does not agree.

[4] Defendants assert that the presumption applies even if the government standard is not safety, but cite no legal authority in support. Doc. 8392 at 5.

a. Design Defect.

Plaintiffs' expert, Dr. Robert McMeeking, has testified that Bard could have developed caudal anchors and penetration limiters sooner that it did. Doc. 7973 at 32. These safety features ultimately were incorporated into Bard's Meridian and Denali filters, and Bard knew as early as March 2006 that one of its competitors had designed anchors to reduce caudal (downward) migration by flipping two of the hooks that secured the filter to the IVC wall. Doc. 7950 ¶ 87 (Ex. 80). A jury reasonably could conclude from this evidence that specific and reasonable alternative design changes were available when Defendants developed the G2X filter.

Defendants note in their reply that Dr. McMeeking does not specify all of the changes that should have been made to the G2X and that Plaintiffs themselves claim the Meridian to be defective even with caudal anchors. Doc. 8392 at 8. But Defendants do not explain why this entitles them to summary judgment. A manufacturer may be liable under § 895.047(1)(a) where the alternative design would have "reduced" the harm posed by the product. Plaintiffs present evidence that caudal anchors help reduce filter migration, which can lead to other complications like those experienced by Mrs. Hyde (tilt, perforation, and fracture). Plaintiffs have presented sufficient evidence of a reasonable alternative design to survive summary judgment.[5]

b. Warning Defect.

Defendants contend that the warning defect claim fails because Plaintiffs identify no "alternative warnings that would have rendered Bard's filter 'safe.'" Doc. 7359 at 13. But this is not the standard. The alternative warning need not render the product safe; instead, the plaintiff must show that the warning "could have . . . reduced or avoided" the

[5] The parties dispute whether Bard's Simon Nitinol filter ("SNF") can serve as an alternative design. Defendants contend that the SNF is a purely permanent filter and, therefore, not a reasonable alternative for the retrievable G2X. Docs. 7359 at 12 n.6 (citing *Godoy v. E.I. du Pont de Nemours & Co.*, 743 N.W.2d 159, 162 (Wis. Ct. App. 2009) (the alternative design cannot make the product "something else")). Plaintiffs counter that the SNF is a suitable alternative because the G2X can also serve as a permanent device and its optional retrievability is not a functional element. Doc. 7952 at 16-17. Given the ruling above, the Court need not resolve this issue for purposes of summary judgment.

harm and that the warning's omission "renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a); *see Lexington*, 2013 WL 4454959, at *8.

Plaintiffs assert that the G2X filter's IFU should have disclosed "the ***increased*** risk of adverse events when compared to the SNF and competitor filters." Doc. 7952 at 21 (emphasis in original). Whether this proposed warning could have reduced or avoided the harm caused by the G2X filter, and whether omission of the warning renders the G2X defective, are questions best resolved by the jury. As explained below, however, Plaintiffs' strict liability failure to warn claim (Count II) fails for lack of causation.

B. Failure to Warn Claims (Counts II and VII).

Defendants contend that the negligent failure to warn claim is barred by the learned intermediary and sophisticated user doctrines.[6] Doc. 7359 at 13-15. Defendants further contend that the warnings Bard provided with the G2X were adequate as a matter of law. *Id.* at 15-16. Finally, Defendants argue that Plaintiffs' strict liability and negligent failure to warn claims fail because the alleged inadequate warning was not the proximate cause of Mrs. Hyde's injuries. *Id.* at 17-18 & n.8. Plaintiffs contend that Wisconsin does not apply the learned intermediary doctrine and that Bard's warnings were inadequate, but do not address causation. Doc. 7952 at 18-22.

The Court can resolve these claims on the element of causation. Regardless of whether Bard's duty to warn extended to Dr. Henry or Mrs. Hyde, Plaintiffs have failed to present any evidence that an inadequate warning caused Mrs. Hyde's injuries, as required under Wisconsin law. *See* Wis. Stat. § 895.047(1)(e) (requiring a plaintiff to

[6] The Wisconsin Supreme Court has not decided whether to adopt the learned intermediary doctrine, and federal courts applying Wisconsin law are split on the issue. *Compare Maynard v. Abbott Labs.*, No. 12-C-0939, 2013 WL 695817 (E.D. Wis. Feb. 26, 2013) ("Wisconsin does not apply the learned intermediary doctrine"), *and Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968 (E.D. Wis. 2009) (declining to apply the doctrine absent some indication that the Wisconsin Supreme Court would do so), *with In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 751-52 (7th Cir. 2018) (concluding that the Wisconsin Supreme Court would adopt the doctrine), *Monson v. Acromed Corp.*, No. 96-C-1336, 1999 WL 1133273, at *20 (E.D. Wis. May 12, 1999) ("manufacturers have a duty to warn only the treating physician"), *and Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 963 (E.D. Wis. 1981) (noting that "the provision of proper warnings to a physician will satisfy the manufacturer's duty to warn").

prove that "the defective condition was a cause" of her injuries); *Kessel v. Stansfield Vending, Inc.*, 714 N.W.2d 206, 211-12 (Wis. Ct. App. 2006) (a plaintiff claiming negligent failure to warn must prove "a causal connection between the defendant's breach of the duty of care and the plaintiff's injury"); *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 876 (Wis. Ct. App. 2004) ("A plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury.").

Plaintiffs argue at length that Bard's warnings for the G2X were inadequate, but present no evidence or argument that an adequate warning would have prevented use of the Bard filter in this case. Doc. 7592 at 19-22; *see* Doc. 8392 at 12. Plaintiffs identify no evidence suggesting that Mrs. Hyde would have chosen not to receive a G2X filter had she been informed the device had an increased risk of adverse events relative to other IVC filters. Nor do Plaintiffs present evidence from which a reasonable inference can be drawn that an adequate warning would have altered Dr. Henry's decision to use a G2X filter. Dr. Henry testified that he did not remember Mrs. Hyde, was not even sure that the filter implanted in her was a G2X, was not certain who made the decision to use a G2X, and had no independent recollection of the procedure, his thought processes, or what may have been explained to Mrs. Hyde regarding potential risks and treatment options. Doc. 7012 at 5, 8, 18-22, 25. Dr. Henry further testified that he tended to trust the FDA more than individual companies and simply did not know whether he would have considered information about complication rates among filters in making the treatment decision for Mrs. Hyde. *Id.* at 10, 13-14. With respect to the Everest clinical study for the G2 filter, Dr. Henry testified that he "may or may not have been swayed by its content" had he read about it. *Id.* at 16.

Plaintiffs argue that there is sufficient evidence that Dr. Henry would have altered his treatment of Mrs. Hyde had he been warned about the risks of Bard filters. Doc. 7953 ¶ 15. But the portion of Dr. Henry's deposition relied on by Plaintiffs (*id.* (citing pages 44, 45, and 47)) do not support Plaintiffs' argument. When asked whether he would have

found "useful" the fact that "Bard determined its Recovery filter migrated three times more than the industry average," Dr. Henry testified: "Right or wrong, I felt that the risks for all of the FDA-approvable devices were – were reasonable and customary, and that I probably wouldn't have deferred or postponed the filter placement in a patient who I felt really needed it." Doc. 7012 at 44-45. The following exchange then occurred:

> Q. As I'm understanding your answer, right or wrong, you assumed that the complication rates among the FDA cleared or approved IVC filters was roughly equivalent?
>
> A. Yes.
>
> Q. If you had learned differently, that would be the type of information that you would have used in your clinical practice, true?
>
> * * *
>
> THE WITNESS: I tend to trust the FDA more than individual companies.

Id. at 45.

Plaintiffs' counsel continued to press:

> Q. Based on your practice of medicine back in 2011, when you're making the decision about which device to implant in a patient's body, you – is it your testimony that you wouldn't be concerned with how frequently those fail?
>
> * * *
>
> THE WITNESS: It was my understanding that the complication rates were low. And, as a physician, you have to look at the big picture. And I think that the – all of the devices were meeting the expectations of the FDA, and I didn't see any deciphering thing to persuade me one way or the other.

Id. at 48.

Plaintiffs argue that Dr. Henry referred to FDA "approval" of a product and obviously did not understand that 510(k) review results only in "clearance." Doc. 7953 at

5-6. This is not entirely correct. As quoted above, counsel posed questions in terms of FDA clearance or approval. Doc. 7012 at 44-45. But even if true, this fact does not provide what is missing in Dr. Henry's testimony – that a warning of greater risks would have affected his decision to use a G2X filter. Plaintiffs also cite the deposition testimony quoted immediately above, focusing particularly on Dr. Henry's statement that "I didn't see any deciphering thing to persuade me one way or the other." *Id*. at 48. But this statement was made right after he said "all of the devices were meeting the expectations of the FDA" (*id.*), and does not constitute evidence that he would have acted differently had he received some different warning from Bard. Finally, Plaintiffs complain that Dr. Henry's counsel instructed him not to answer questions about how he would have reacted to facts found in various Bard internal documents (Doc. 7953 at 6), but the Court previously held that this instruction was proper under Wisconsin law (Doc. 8180).

Because Plaintiffs present no evidence that Mrs. Hyde or Dr. Henry would have acted differently in the face of different warnings by Bard, summary judgment is warranted on the failure to warn claims. *See Kurer*, 679 N.W.2d at 876 ("Absent proof that a more complete or explicit warning would have prevented Kurer's use of Loestrin, she cannot establish that [the] alleged failure to warn was the proximate cause of her injuries."); *Menges*, 61 F. Supp. 2d at 830 ("[A] plaintiff must not only show that the manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff."); *Hanson v. Boston Sci. Corp.*, No. 2:13-CV-10653, 2016 WL 1448868, at *5 (S.D.W. Va. Apr. 12, 2016) (applying Wisconsin law and finding the causation evidence insufficient where it "require[d] a reasonable juror to speculate, based only on mere *possibility*, that [the doctor] would have altered her decision to prescribe the product simply because she would have *considered* an additional factor in her risk/benefit calculus" (emphasis in original)).

/ / /

C. Misrepresentation and Fraud Claims (Counts VIII and XII-XIV).

Plaintiffs assert claims for negligent and fraudulent misrepresentation, fraudulent concealment, and fraudulent trade practices in violation of Wis. Stat. § 100.18. Doc. 364 ¶¶ 218-28, 245-321. The parties agree that an essential element of each of these claims is reliance or causation. Doc. 7592 at 22. Defendants argue that summary judgment is warranted because there is no evidence showing that Mrs. Hyde or Dr. Henry relied on any representations by Bard or that Bard's public statements caused Mrs. Hyde's injuries. Docs. 7359 at 19-20. The Court agrees.

Mrs. Hyde admits that she never spoke to anyone at Bard or received any information from Bard. Doc. 7953 ¶ 27. She presents no evidence that Dr. Henry relied on any information Bard provided about its IVC filters, through its sales force or otherwise. Dr. Henry testified that he tends to trust the FDA more than individual companies and was comfortable using FDA-approved medical devices. Doc. 7950 ¶ 181. Absent some evidence Dr. Henry or Mrs. Hyde relied on representations made by Bard, or that Bard's alleged concealment of information caused Plaintiffs' injuries, the fraud and misrepresentation claims fail as a matter of law. *See Staudt v. Artifex Ltd.*, 16 F. Supp. 2d 1023, 1030 (E.D. Wis. 1998) (misrepresentation and concealment claims require reliance resulting in damage).

Plaintiffs contend that Bard committed fraud on the FDA, and that Dr. Henry's trust in the FDA constitutes reliance on Bard's misrepresentations and concealment. Doc. 7952 at 22-24. But Plaintiffs present no legal authority to support this contention, and any claim based solely on fraud on the FDA is preempted. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Plaintiffs' misrepresentation and fraud claims fail for lack of reliance and causation.

IT IS ORDERED:

1. The following claims are **dismissed** based on Plaintiffs' withdrawal of the claims before Defendants moved for summary judgment: manufacturing defect (Counts I and V) and breach of express warranty (Count X).

2. Defendants' motion for partial summary judgment (Doc. 7359) is **granted in part and denied in part**. The motion is granted with respect to Plaintiffs' claims for failure to warn (Counts II and VII), failure to recall (Count VI), misrepresentation, concealment, and fraud (Counts VIII and XII-XIV), and breach of implied warranty (Count XI). The motion is denied with respect to the strict liability design defect claim (Count III). This claim, along with the claims for negligent design (Count IV), negligence per se (Count IX), loss of consortium (Count XV), and punitive damages, remain for trial.

3. By **August 10, 2018**, the parties shall confer and provide a joint report to the Court on whether there is a means for determining Mrs. Hyde's filter type prior to trial, or whether this will be an issue for the jury to decide.

Dated this 26th day of July, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **CASE MANAGEMENT ORDER NO. 36**

The Court has reviewed the parties' memoranda on Plaintiff Debra Mulkey's status and the possibility of trying the Tinlin case in November 2018. Docs. 11951, 11952. The memorandum on Ms. Mulkey makes clear that her case should not be scheduled for trial in November. She continues to undergo medical testing attempting to identify the cause of her concerning health issues, and scheduling her for the stress of a three-week trial in November would be unwise. The Court will try Ms. Mulkey's case in 2019.

The Court had fully intended to try a fourth bellwether trial in November, but the Court's grant of summary judgment in the Kruse case and the unavailability of Ms. Mulkey for trial this year mean that the only remaining bellwether plaintiff is Debra Tinlin. Unfortunately, much of the case-specific discovery and expert disclosures required for the Tinlin trial have not been completed. Plaintiffs propose an aggressive schedule to have the Tinlin case ready for trial in November, but the Court concludes that the schedule is unrealistic. A year's worth of medical records for Plaintiff Tinlin's many medical conditions will need to be collected, many treating physicians likely will need to

be deposed, plaintiff-specific expert reports must be prepared and disclosed, expert depositions must be completed, and *Daubert* and summary judgment motions must be briefed and decided. For a trial to begin on November 5, 2018, the Court would need to rule on the *Daubert* and summary judgment motions in early October, something that would be very difficult in light of the Court's administrative responsibilities that month and the fact that the Hyde bellwether trial will not end until October 5.

The Court is reluctant to lose the November bellwether trial slot, but circumstances make a Tinlin trial in November unreasonable. As a result, the Court will plan to try the Tinlin and Mulkey cases in February and May of 2019. The Court will decide the order of the trials, and the dates for the trial in May, after the Hyde trial.

The parties shall follow this schedule in preparing the Tinlin case for trial:

1. Plaintiff shall provide an updated provider list and executed medical authorizations to Defendants by **August 10, 2018**.

2. The parties shall obtain updated medical records from known treaters and newly identified treaters by **September 28, 2018**.

3. The parties shall identify treating physicians and fact witnesses to be deposed, and shall complete the depositions on a rolling basis, by **October 5, 2018**.

4. Plaintiff's case-specific expert disclosures shall be completed by **September 28, 2018**.

5. Defendants' case-specific expert disclosures shall be completed by **October 26, 2018**.

6. Case-specific experts shall be deposed by **November 16, 2018**.

7. Dispositive and *Daubert* motions shall be filed by **December 7, 2018,** responses by **December 28, 2018,** and replies by **January 11, 2019**.

Dated this 2nd day of August, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC
Carol Kruse, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-15-01634-PHX-DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters. The MDL Plaintiffs have received implants of Bard IVC filters and claim that they are defective and have caused Plaintiffs to suffer serious injury or death.

One of the MDL cases is brought by Plaintiff Carol Kruse, who had a Bard filter implanted nine years ago. Ms. Kruse's case has been selected as one of several bellwether cases. Defendants have filed a motion for summary judgment. Doc. 7341.

The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will grant the motion.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. An IVC filter is a device implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves multiple versions of Bard IVC filters – the Recovery, G2, G2X, Eclipse, Meridian, and Denali. These are spider-shaped devices that have multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with hooks that attach to the IVC wall and curved arms to catch or break up blood clots. Each of these filters is a variation of its predecessor.

The MDL Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have higher risks of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs further allege that Bard failed to warn patients and physicians about these higher risks. Defendants dispute these allegations, contending that Bard filters are safe and effective, that their complication rates are low and comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters.

II. Plaintiff Carol Kruse.

Plaintiff Kruse has a history of blood clots. Before knee surgery in July 2009, she had a Bard G2 filter implanted to mitigate the risk of a pulmonary embolism during or after surgery. Dr. Shanon Smith implanted the filter without incident. Dr. Smith attempted to remove the filter on April 7, 2011, but was unsuccessful because the filter had tilted and perforated the IVC wall. The filter remains embedded in Plaintiff's IVC.

Plaintiff filed suit against Bard on April 6, 2015. She asserts various claims under Nebraska law.[1] The following claims remain: failure to warn (Counts II and VII), design defects (Counts III and IV), failure to recall (Count VI), misrepresentation (Counts VIII

[1] The parties agree that Nebraska law applies to Plaintiff's claims. Docs. 7348 at 18 n.7, 8009 at 3 & n.2.

and XII), negligence per se (Count IX), concealment (Count XIII), consumer fraud and unfair trade practices (Count XIV), and punitive damages. *See* Doc. 364 (master complaint).[2]

Defendants move for summary judgment on various grounds. Doc. 7348. Plaintiff opposes the motion. Doc. 8009. For reasons stated below, the Court will grant summary judgment on statute of limitations grounds.[3]

III. Summary Judgment Standard.

A party seeking summary judgment "bears the initial responsibility of informing the court of the basis for its motion and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The evidence must be viewed in the light most favorable to the nonmoving party, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), and all justifiable inferences are drawn in that party's favor because "[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions," *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). To avoid summary judgment, the factual dispute must be genuine – that is, the evidence must be sufficient for a reasonable jury to return a verdict for the nonmoving party. *Anderson*, 477 U.S. at 248.

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[2] The master complaint is the operative pleading in this MDL. It asserts 17 claims and seeks both compensatory and punitive damages. *Id.* ¶¶ 166-349. The allegations and claims asserted in the master complaint have been deemed pled in Plaintiff's previously filed individual complaint. Doc. 1485 at 1; *see* Doc. 1, Case No. 15-CV-01634-PHX-DGC. Plaintiff is not pursuing the claims for manufacturing defect (Counts I and V), breach of warranty (Counts X and XI), loss of consortium, wrongful death, and survival (Counts XV-XVII). Doc. 8009 at 2 n.1.

[3] This bellwether case was set for trial in September 2018. Doc. 11659. In mid-July, the Court informed the parties that it had concluded that summary judgment must be granted in favor of Defendants. Doc. 11839. The Court stated that it would issue an order granting summary judgment and setting forth its analysis. *Id.* This is the order.

IV. Discussion.

A. Nebraska's Statute of Limitations and Discovery Rule.

Under Nebraska law, civil actions generally must be brought within the time period prescribed by the applicable statute of limitations. Neb. Rev. Stat. § 25-201. Nebraska's statute of limitations for product liability actions requires that such actions, other than asbestos-related suits, "be commenced within four years next after the date on which the death, injury, or damage complained of occurs." Neb. Rev. Stat. § 25-224(1).

Nebraska courts have adopted a discovery rule for § 25-224(1). *See Condon v. A. H. Robins Co.*, 349 N.W.2d 622, 623-27 (1984). Under this rule, an injury "occurs" within the meaning of the statute, and the limitations period begins to run, when the plaintiff first "discovers, or in the exercise of reasonable diligence should have discovered, the existence of [the] injury[.]" *Id.* at 627. "Discovery refers to the fact that one knows of the existence of an injury . . . and not that one knows who or what may have caused that injury[.]" *Thomas v. Countryside of Hastings, Inc.*, 524 N.W.2d 311, 313 (Neb. 1994). Similarly, "one need not know the full extent of one's damages before the limitations period begins to run[.]" *Gordon v. Connell*, 545 N.W.2d 722, 726 (Neb. 1996).

B. Plaintiff's Claims Are Time Barred Under § 25-224(1).

Because Plaintiff filed suit on April 6, 2015, her claims are time barred if the four-year limitations period set forth in § 25-224(1) began to run on or before April 5, 2011. Defendants argue that Plaintiff discovered her injury no later than March 14, 2011, when Plaintiff underwent a pre-op exam before the attempted removal of the G2 filter. Doc. 7348 at 6-8. Plaintiff contends that her claims are timely because she did not discover her injury until after the removal procedure on April 7, 2011. Doc. 8009 at 5-8.

The Court agrees with Defendants. The undisputed evidence shows that Plaintiff clearly knew of the existence of the injury well before then. Plaintiff began experiencing new and unfamiliar abdominal pain only a few days after the filter was implanted in 2009. Doc. 7350-4 at 12. Plaintiff had not felt this pain before the filter was implanted,

id., and she continued to have occasional abdominal pain when she twisted and bent certain ways, *id.* at 18. The abdominal pain was not related to digestive problems or Plaintiff's low back pain. *Id.* at 17-18.

Sometime in 2009 or 2010, Plaintiff saw a TV ad with a phone number for people with IVC filters to call if they were having "problems" with their filters. *Id.* at 4-8; Doc. 7350-1 at 4. Plaintiff called the number. Doc. 7350-4 at 3-5.

In late 2010, Plaintiff discussed her abdominal pain and the fact that she had an IVC filter with Kristi Eggers, a nurse who worked with local doctors and with Plaintiff at a nursing home. *Id.* at 13. Plaintiff testified about her conversation with Eggers as follows:

> Q. When is the first time you remember speaking to a doctor about having your IVC filter removed after it was implanted?
>
> A. That would have been – her name is Kristi Eggers, and she was [a] nurse practitioner . . . . *And in our conversation I told her that I had a filter, and, you know, I had this infrequent pain*, and she said, "Well, you know, can you have the filter removed?" And that's kind of how we got to talking about it. So I called Dr. Smith and said let's see if we can get it out.

Doc. 7350-4 at 13-14 (emphasis added).

Plaintiff underwent a pre-op exam on March 14, 2011. Doc. 7350-2 at 13-15. The progress note for that exam, signed by Eggers, states: "[Patient] is planning to have [the] IVC filter removed. This has been causing her pain for the last 3-4 months." Doc. 7350-2 at 13. When shown this progress note during her deposition, Plaintiff did not dispute that it said the G2 filter had been causing her pain. *Id.* at 16. The following exchange then occurred:

> Q. At this time period you were experiencing the abdominal pain that you described before where it would hurt when you twisted or bent certain ways; right?
>
> A. Correct.

Q. And you were going in to get this pre-op clearance to have your IVC filter removed?

A. Yes.

Q. And at this time period you had had conversations with Kristi Eggers about potentially my IVC filter is causing that pain; right?

A. Yes, abdominal pain.

Id. at 18-19.

This evidence shows that Plaintiff knew of her abdominal pain before the removal procedure on April 7, 2011, and even suspected that it was caused by the G2 filter. For purposes of § 25-224(1), Plaintiff discovered the existence of her injury – and the limitations period began to run – more than four years before she filed suit. *See Alston v. Hormel Foods Corp.*, 730 N.W.2d 376, 385 (Neb. 2007) (explaining that the discovery rule tolls the statute of limitations only where the plaintiff "is wholly unaware that he or she has suffered an injury or damage"). The Court will grant Defendants' summary judgment motion on statute of limitations grounds. *See Gordon*, 545 N.W.2d at 726 (affirming summary judgment and finding that the plaintiff discovered his injury within the limitations period where "he certainly knew that he had been injured, because he continued to experience pain").

Plaintiff contends that the date she discovered her injury is a disputed issue of fact that should be left to the jury. Doc. 8009 at 5. But Plaintiff does not dispute the facts set forth above. *See* Doc. 7959 ¶¶ 6-7, 13-15. Those facts, even when construed in her favor, show that Plaintiff experienced previously unknown pain after the filter implant, continued to have the pain, albeit infrequently, called the IVC number designated for people with filter problems, mentioned the pain to Kristi Eggers, suggested to Eggers that the pain was caused by the filter, and scheduled an appointment to have the filter removed. When Plaintiff met with Eggers before the removal procedure on March 14, 2011, Eggers stated in the progress note that the filter "has been causing her pain for the

last 3-4 months." Doc. 7350-2 at 13. No jury reasonably could find that Plaintiff first discovered her injury on April 7, 2011.

In claiming that she "neither knew nor had reason to know that her pain was filter-related in March 2011," Plaintiff cites the following exchange at the end of her deposition:

> Q. Did you know or have reason to know that pain was filter related in March of 2011?
>
> A. No.
>
> Q. When was the first time that you had any reason to believe that your filter was – there is anything wrong with your filter?
>
> A. When the filter retrieval was unsuccessful and Dr. Smith came in and said, you know, the filter is tilted and that's why we couldn't get it out.

Docs. 7959 at 6, 8009 at 6 (citing Doc. 7959-1 at 27). These statements contradict her prior testimony about the G2 filter causing her abdominal pain and the March 2011 progress note. The statements do not present "a sufficient disagreement to require submission to a jury." *Kennedy v. Applause, Inc.*, 90 F.3d 1477, 1481 (9th Cir. 1996) (quoting *Anderson*, 477 U.S. at 251-52); *see Craig v. Cty. of Santa Clara*, No. 17-CV-02115-LHK, 2018 WL 3777363, at *16 (N.D. Cal. Aug. 9, 2018) (citing *Kennedy* and finding that deposition testimony did not create a triable issue where it flatly contradicted prior statements and other evidence); *Watkins v. City of San Jose*, No. 15-CV-05786-LHK, 2017 WL 1739159, at *13 (N.D. Cal. May 4, 2017) (same); *Lansmont Corp. v. SPX Corp.*, No. 5:10-CV-05860 EJD, 2012 WL 6096674, at *4 (N.D. Cal. Dec. 7, 2012) ("To the extent [the] deposition testimony is internally inconsistent, it does not itself create a dispute of material fact because the former statement is rejected as self-serving, vague and contrary to the remaining evidence.").

Even if the Court were to credit these closing questions in Plaintiff's deposition, they say only that Plaintiff did not know her pain was caused by the filter until after the

unsuccessful removal procedure on April 7, 2011. But that knowledge is not required to satisfy the discovery rule and trigger the statute of limitations period under Nebraska law. "Discovery refers to the fact that one knows of the existence of an injury . . . and not that one knows who or what may have caused that injury[.]" *Thomas*, 524 N.W.2d at 313. "It is not necessary that a plaintiff have knowledge of the exact nature or source of the problem, but only that a problem existed." *Reinke Mfg. Co. v. Hayes*, 590 N.W.2d 380, 390 (Neb. 1999); *see Lindsay Mfg. Co. v. Universal Sur. Co.*, 519 N.W.2d 530, 504-05 (Neb. 1994). Thus, even if Plaintiff did not suspect that her abdominal pain was filter-related, summary judgment would be warranted because there is no dispute that she knew of her abdominal pain more than four years before she filed suit. *See Gordon*, 545 N.W.2d at 726.

Plaintiff presents a declaration in which she asserts that she had no reason to know that the G2 filter had caused any injury until Dr. Smith attempted to remove the device. Doc. 7959-1 at 31. This assertion does not help Plaintiff for the same reason – she did not need to know the cause of her pain for the limitations period to be triggered.

Similarly, it is immaterial whether Plaintiff knew before the removal procedure that the G2 filter had tilted, migrated, perforated her IVC, and fractured. Docs. 7959-1 at 31, 8009 at 7. A plaintiff "need not know the full extent of [her] damages before the limitations period begins to run[.]" *Gordon*, 545 N.W.2d at 726. Regardless of when Plaintiff became aware that the G2 filter had failed, she "discovered facts sufficient to put [her] on notice of [the] injury well with the statutory period of limitations." *Reinke*, 590 N.W.2d at 390.

Plaintiff's declaration contains other assertions the Court must address. She does not dispute in her declaration that she and Eggers discussed her abdominal pain, her IVC filter, and the filter's removal before March 14, 2011. Doc. 7959-1 at 30-31. But she states, nonetheless, that the reason she scheduled the removal procedure "was not because [she] knew that or believed at that time that the filter was causing any pain, but simply because it had been brought to her attention that the filter was no longer needed and it

was a convenient time for [her] to have the procedure." *Id.* She similarly states that she met with Eggers for the pre-op exam "only because [she] thought the filter was no longer needed and because April 2011 was a convenient time for [her] to have the procedure." *Id.* at 31. These statements are wholly inconsistent with Plaintiff's deposition testimony that she had conversations with Eggers about the G2 filter causing her abdominal pain and, as a result of the conversation, made an appointment to have the filter removed. Doc. 7350-2 at 13-15, 19.

"The general rule in the Ninth Circuit is that a party cannot create an issue of fact by an affidavit contradicting [her] prior deposition testimony." *Kennedy v. Allied Mut. Ins. Co.*, 952 F.2d 262, 266 (9th Cir. 1991) (citations omitted). "This sham affidavit rule prevents a party who has been examined at length on deposition from raising an issue of fact simply by submitting an affidavit contradicting [her] own prior testimony, which would greatly diminish the utility of summary judgment as a procedure for screening out sham issues of fact." *Yeager v. Bowlin*, 693 F.3d 1076, 1080 (9th Cir. 2012) (quoting *Kennedy*, 952 F.2d at 266); *see Van Asdale v. Int'l Game Tech.*, 577 F.3d 989, 998 (9th Cir. 2009) (explaining that the sham affidavit rule is necessary to maintain the principle that the summary judgment procedure is an integral part of the federal rules). Because a court is not to weigh conflicting evidence or make credibility determinations on summary judgment, however, the sham affidavit rule "should be applied with caution." *Van Asdale*, 577 F.3d at 998 (citation omitted).

As noted above, certain statements in Plaintiff's declaration flatly contradict her prior deposition testimony. There is "clear and unambiguous" inconsistency, *Yeager*, 693 F.3d at 1080, between Plaintiff's deposition testimony and the conclusory assertion in her declaration that "[t]he first time [she] knew or had a reasonable basis for knowing that the Bard G2 filter . . . had caused any injury was after Dr. Smith attempted to remove the filter on April 7, 2011." Doc. 7959-1 at 31. This is not a case of "newly-remembered facts, or new facts, accompanied by a reasonable explanation[.]" *Yeager*, 693 F.3d at 1081. Nor can the declaration be construed as simply "clarifying prior testimony

elicited by opposing counsel on deposition and minor inconsistencies that result from an honest discrepancy[.]" *Van Asdale*, 577 F.3d at 999. Plaintiff affirmatively testified during her deposition that she talked to Eggers about the G2 filter causing her pain. Doc. 7350-4 at 13-15, 19. This testimony renders implausible Plaintiff's subsequent declaration that she had no reason to suspect that the G2 filter was the cause of her pain and scheduled the removal procedure only because the filter was no longer needed and it was a convenient time for the procedure. Doc. 7350 at 30-31. The Court therefore will disregard the declaration in this respect. *See Yeager*, 693 F.3d at 1081; *Welsh v. Trimac Transp. Servs. (W.) Inc.*, No. CV-11-01625-PHX-ROS, 2014 WL 12617737, at *4 (D. Ariz. Mar. 31, 2014) (finding statements in a summary judgment affidavit to be a sham where the plaintiff offered no explanation as to why he stated to the contrary in his deposition testimony); *see also Momsen v. Neb. Methodist Hosp.*, 313 N.W.2d 208, 213 (Neb. 1981) ("Where a party without reasonable explanation testifies to facts materially different concerning a vital issue, the change clearly being made to meet the exigencies of pending litigation, such evidence is discredited as a matter of law and should be disregarded." (citations omitted)).

Plaintiff argues that Defendants' own expert in interventional radiology has opined that Plaintiff's other health problems could have been a cause of her pain. Doc. 8009 at 7. But that opinion does not change the fact that Plaintiff herself felt pain she had not experienced before the filter was implanted, and discovery under Nebraska law "refers to the fact that one knows of the existence of an injury . . . and not that one knows who or what may have caused that injury[.]" *Thomas*, 524 N.W.2d at 313. Nor does it change the fact that Plaintiff called the IVC legal number for people with filter problems, talked to Eggers about the pain she was experiencing and her suspicion that is was caused by the filter, scheduled to have the filter removed, and had a pre-op meeting with Eggers that resulted in a progress note stating that Plaintiff's filter "has been causing her pain for the last 3-4 months." Doc. 7350-2 at 13.

Finally, Plaintiff asserts that the statute of limitations defense should be

disregarded because this is a bellwether case. But the Court cannot conclude that legal defenses available under Nebraska law, and that would apply if this case were tried in Nebraska federal court, are somehow inapplicable because this is a bellwether trial. The Court is to apply the law of the transferee district when deciding cases in this MDL proceeding. *See In re Zicam Cold Remedy Mktg., Sales Practices, & Prods. Liab. Litig.*, 797 F. Supp. 2d. 940, 941 (D. Ariz. 2011) (citing *Ferens v. John Deere Co.*, 494 U.S. 516, 525 (1990)).[4]

IT IS ORDERED:

1. The following claims are **dismissed** based on Plaintiff's withdrawal of the claims before Defendants moved for summary judgment: manufacturing defect (Counts I and V), breach of warranty (Counts X and XI), loss of consortium, wrongful death, and survival (Counts XV-XVII).

2. Defendants' motion for summary judgment (Doc. 7341) is **granted** on the remaining claims: failure to warn (Counts II and VII), design defect (Counts III and IV), failure to recall (Count VI), misrepresentation (Counts VIII and XII), negligence per se (Count IX), concealment (Count XIII), consumer fraud and unfair trade practices (Count XIV), and punitive damages.

Dated this 17th day of August, 2018.

David G. Campbell
Senior United States District Judge

[4] Plaintiff asserts that Defendants have not moved for summary judgment on the design defect claims (Counts III and IV). Doc. 8009 at 2. Defendants admit that they inadvertently omitted these counts from the introduction section of their motion, but note that the motion otherwise makes clear that, with respect to the statute of limitations argument, Defendants seek summary judgment as to all of Plaintiff's claims. Plaintiff had a full and fair opportunity to respond to that argument. The Court finds that the Nebraska statute of limitations for product liability cases applies to all of Plaintiff's claims. Given this ruling, the Court need not address Defendants' other summary judgment arguments.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC
Lisa Hyde and Mark E. Hyde, a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00893-PHX-DGC **ORDER**

The case brought by Plaintiffs Lisa and Mark Hyde is set for a bellwether jury trial on September 18, 2018. During the final pretrial conference held on September 6, 2018, it became clear that the parties disagree on whether Plaintiffs' negligence per se claim is impliedly preempted under 21 U.S.C. § 337(a). The issue was raised and briefed by the parties in their proposed final pretrial order and jury instructions. Docs. 12388 at 8-12, 12438 at 54-61. The Court asked the parties during the pretrial conference whether they required further briefing and whether they wished to have this issue resolved before trial. Counsel for both sides stated that no further briefing was needed and that a ruling before trial would be helpful.

For the reasons stated below, the Court finds that the negligence per se claim is preempted. This conclusion is purely legal – it is not affected by the evidence that would be presented at trial. As a result, the Court concludes that it should enter judgment on this claim before trial under Rule 56 of the Federal Rules of Civil Procedure. Although decisions under that rule normally are made in response to a formal motion for summary judgment, the rule makes clear that the Court may enter summary judgment *sua sponte*, provided the parties are notified of the Court's intention to make a dispositive decision and have an opportunity to respond. *See* Fed. R. Civ. P. 56(f); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 326 (1986) ("district courts are widely acknowledged to possess the power to enter summary judgments *sua sponte*, so long as the losing party was on notice that she had to come forward with all of her evidence"). In this instance, the question is purely one of law, the parties have been fully heard, and the parties seek a decision before trial. Such a decision will enable the parties to allocate their time and evidence to the issues to be considered by the jury.[1]

I. Background.

Plaintiff Lisa Hyde received a Bard IVC filter implant in 2011. In 2014, she learned that the filter had tilted, perforated the IVC wall, and fractured. The filter and fractured limbs were removed three months later.

Mrs. Hyde and her husband assert various claims. Doc. 364; Doc. 1, Case No. CV-16-00893. Applying Wisconsin law, the Court granted summary judgment to Defendants on several claims. Doc. 12007. Plaintiffs continue to assert claims for strict liability design defect (Count III), negligent design (Count IV), negligence per se (Count IX), loss of consortium (Count XV), and punitive damages. *Id.* at 19.[2]

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[1] Another approach would be to treat this issue as a motion by Defendants for judgment as a matter of law under Rule 50. Although the standard for deciding such a motion is the same as the standard under Rule 56, the Ninth Circuit has held that a Rule 50 motion cannot be made before trial. *See McSherry v. City of Long Beach*, 423 F.3d 1015, 1019-22 (9th Cir. 2005). The Court accordingly will enter judgment under Rule 56.

[2] Defendants have explained that they did not seek summary judgment on the negligence per se claim because they did not know the basis for the claim until the parties

II. Discussion.

Under Wisconsin law, negligence per se is a form of negligence that results from violation of a statute. *See Friederichs v. Huebner*, 329 N.W.2d 890, 917 (Wis. 1983). For the violation of a safety statute to constitute negligence per se, the plaintiff "must show: (1) the harm inflicted was the type the statute was designed to prevent; (2) the person injured was within the class of persons sought to be protected; and (3) there is some expression of legislative intent that the statute become a basis for the imposition of civil liability." *Tatur v. Solsrud*, 498 N.W.2d 232, 235 (D. Wis. 1993) (citing *Walker v. Bignell*, 301 N.W.2d 447, 454 (Wis. 1981)).

Plaintiffs do not allege violation of a Wisconsin statute as part of their negligence per se claim. Rather, they contend that Defendants violated various provisions of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and related federal regulations, in designing the Bard filter. Docs. 12388 at 8-9 (final pretrial order), 12400 at 4-7 (trial brief), 12438 at 54-59 (proposed jury instructions). Specifically, Plaintiffs allege violations of 21 U.S.C. §§ 321, 331, and 352, and 21 C.F.R. §§ 803, 806.1, 820.100, 820.198, and 820.250. *Id.*; *see* Doc. 364 ¶ 231.

As noted above, the third element of Wisconsin's negligence per se claim requires "some expression of legislative intent that the statute become a basis for the imposition of civil liability." *Tatur*, 498 N.W.2d at 235. As other courts have recognized, however, "[f]ar from containing an expression that FDA regulations are intended to form the basis for civil liability, the [FDCA] expresses the opposite intention." *Cali v. Danek Med., Inc.*, 24 F. Supp. 2d 941, 954 (W.D. Wis. 1998). Under § 337(a), "[v]iolations of the FDA are enforceable only by the United States." *Id.* "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Thus, "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a

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prepared the proposed final pretrial order.

claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist." *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011) (citation omitted); *see Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) (noting that under § 337(a) "no private right of action exists for a violation of the FDCA").

In *Buckman*, the Supreme Court held that a state law claim that a defendant made fraudulent statements to the FDA, in violation of the FDCA, was impliedly preempted by § 337(a) because the claim "exist[ed] solely by virtue" of FDCA requirements and therefore "would not be relying on traditional state tort law which had predated the [FDCA]." 531 U.S. at 353. The same is true here. Plaintiffs' "claim of negligence per se would not exist prior to the enactment of the FDCA . . . because the claim only alleges violation of that law." *Leonard*, 2011 WL 3652311, at *8. As in *Buckman*, Plaintiffs' "negligence per se claim (or, more appropriately characterized, [their] negligence claim based solely on violations of . . . FDA regulations) is impliedly preempted by the FDCA." *Grant v. Corin Grp. PLC*, No. 3:15-CV-169-CAB-BLM, 2016 WL 4447523, at *4 (S.D. Cal. Jan. 15, 2016); *see Connelly v. St. Jude Med., Inc.*, No. 5:17-cv-02005-EJD, 2017 WL 3619612, at *5 (N.D. Cal. Aug. 23, 2017) (negligence per se claim preempted where it was "based entirely on violations of the FDCA and its implementing regulations"); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 862 (W.D. Tenn. 2015) ("If Plaintiffs claim negligence based solely on Defendants' failure to comply with federal law or solely on illegal off-label promotion (i.e. negligence per se), Plaintiffs' claims are impliedly preempted under *Buckman*."); *Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014) ("[A] negligence per se claim alleging violation of the FDCA is nothing more than a private right of action under the FDCA for damages. Since the latter is not available as a result of § 337(a), the Court finds that the former is preempted as well."); *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1200 (M.D. Fla. 2013) ("Plaintiff's attempt to recast a claim for violation of the FDCA as a state-law negligence claim is impliedly barred by § 337(a)."); *Franklin v.*

Medtronic, Inc., No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) ("[T]o the extent that Plaintiff seeks to ground her negligence per se . . . claim[] on allegations that Defendant violated the FDCA – namely, by selling a misbranded and adulterated product – these claims are impliedly preempted pursuant to 21 U.S.C. § 337(a)."); *Talley v. Danek Med., Inc.*, 7 F. Supp. 2d 725, 731 (E.D. Va. 1998) ("[T]he FDCA expressly prohibits the bringing of a private cause of action under the Act. To allow a state negligence per se action based upon alleged violations of the FDCA would defeat the purpose of that prohibition.").

Plaintiffs' citation of *Garross v. Medtronic, Inc.*, 77 F. Supp. 3d 809, 816 (E.D. Wis. 2015), is not persuasive. Doc. 12388 at 9-10. The plaintiff in that case did not bring a negligence per se claim, but instead asserted traditional common law torts such as design defect, failure to warn, and negligence. *Garross*, 77 F. Supp. 3d at 813. Those claims were not impliedly preempted under *Buckman* "because none of them [arose] solely from a violation of federal law; rather, each [arose] from an independent, well-recognized duty owed under state law." *Id.* at 816; *see also Hoffmann v. Wis. Elec. Power Co.*, 664 N.W.2d 55, 62 (Wis. 2003) (noting that "the enactment of safety statutes . . . does not abolish the duty arising under common-law negligence"). In this case, Plaintiffs retain and will assert at trial a common law negligent design claim; that claim is not affected by this ruling.

Plaintiffs cite cases holding that violations of FDCA regulations may support negligence per se claims in Wisconsin. Doc. 12388 at 9-10 (citing *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 964 (E.D. Wis. 1981) (pre-*Buckman* decision holding that violation of federal regulation for prescription drug labeling supported negligence per se claim under Wisconsin law); *Marvin v. Zydus Pharms. (USA) Inc.*, 203 F. Supp. 3d 985, 992 (W.D. Wis. 2016) (finding that plaintiffs may bring a negligence per se claim under Wisconsin law based on a violation of federal medication guide regulations); Doc. 12400 at 13 (citing *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 874 (Wis. Ct. App. 2004) ("In Wisconsin, violations of the FDA regulations may constitute negligence

per se.")). But these cases are squarely at odds with § 337(a). The plain language of that section and the *Buckman* decision indicate that such claims fail. *See Dunbar*, 2014 WL 3056026, at *6. Even if state law recognizes the claims, federal law preempts them. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (finding state law claim preempted where the plaintiff was not suing under state law for conduct that happens to violate the FDCA, but instead is suing solely "*because* the conduct violates the FDCA.") (emphasis in original). This Court reached the same conclusion in previous bellwether cases. *See* Docs. 8874 at 14-18, 10404 at 14-17 (finding negligence per se claims impliedly preempted in the Booker and Jones bellwether cases).

IT IS ORDERED that judgment is entered in favor of Defendants on Plaintiffs' negligence per se claim (Count IX).

Dated this 11th day of September, 2018.

David G. Campbell
Senior United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC
Lisa Hyde and Mark E. Hyde, a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00893-PHX-DGC **ORDER**

The case brought by Plaintiffs Lisa and Mark Hyde is set for a bellwether jury trial on September 18, 2018. Defendants seek reconsideration of the Court's summary judgment ruling that Wisconsin's product liability statute, Wis. Stat. § 895.047, does not create a rebuttable presumption that the Bard IVC filter is not defective. Doc. 12007 at 10-12. The issue was addressed by the parties in their trial briefs and proposed jury instructions, and discussed at the final pretrial conference held on September 6, 2018. *See* Docs. 12358 at 11-14, 12438 at 49, 12400 at 11-12. Defendants stated in their trial brief that the issue warrants more detailed briefing (Doc. 12358 at 13), but made clear at the pretrial conference that the materials submitted are sufficient. For the reasons stated

below, the Court will deny Defendants' request for reconsideration.

Section 895.047(3)(b) creates a rebuttable presumption that a product is not defective if it complied with "relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency[.]" Defendants argued in their summary judgment motion that the design of the Bard filter and the warnings provided with the device are presumed to be non-defective because Bard complied with the FDA's 510(k) process. Doc. 7359 at 12. The Court rejected this argument because 510(k) review focuses on equivalence, not safety. Doc. 12007 at 11. The Court noted that Defendants had cited no legal authority for the proposition that the presumption applies even if the government standard is not safety. *Id.* at 12 n.4.

Defendants' recent briefing relies on *Kilty v. Weyerhaeuser Co.*, No. 16-CV-515-WMC, 2018 WL 2464470 (W.D. Wis. June 1, 2018), a decision issued after summary judgment briefing was complete. Defendants argue that it would be incorrect to conclude that only safety regulations are entitled to the presumption of non-defectiveness under § 895.047(3)(b), but *Kilty* did not consider this issue. The regulations in *Kilty* were safety standards – regulations enacted by the National Institute of Occupational Safety and Health and the U.S. Bureau of Mines concerning the performance and quality of respiratory equipment used to protect workers against asbestos exposure. 2018 WL 2464470, at *3 (discussing regulations set forth in 30 C.F.R. 11 *et seq.*); *see also Commercial Union Ins. Co. v. United States*, No. CIV.A. 87-3913, 1988 WL 92081, at *1 (E.D. La. Aug. 19, 1988) (explaining that "Title 30 of the Code of Federal Regulations establishes a schedule for testing to insure compliance with safety standards").

The fact that the safety standards in *Kilty* were sufficient to meet § 895.047(3)(b)'s "relevant standards" requirement, Defendants contend, "does not mean that 'safety' is a necessary condition under the statute." Doc. 12358 at 12 n.17. But *Kilty* does not address this issue one way or the other, and Defendants cite no authority holding that the Wisconsin presumption arises from non-safety regulations. Surely the statute's reference to "*relevant* standards, conditions, or specifications" requires some connection to the

alleged defect. Wis. Stat. § 895.047(3)(b) (emphasis added). For example, it would make no sense to hold that an auto manufacturer's compliance with federally-promulgated fuel efficiency standards gives rise to a presumption of non-defectiveness in a roll-over case where the plaintiff claims that the car's suspension was defective. *Kilty*'s reliance on federal regulations that clearly concerned the safety of respiratory equipment does nothing to suggests that this Court erred when it held that Defendants' compliance with the 510(k) process does give rise to the statutory presumption. As the Court noted in its summary judgment ruling, other cases specifically have held that § 895.047(3)(b) creates no rebuttable presumption for medical devices cleared under 510(k) review because that review does not concern the safety of the product. *See Hall v. Boston Sci. Corp.*, No. 2:12-CV-08186, 2015 WL 874888, at *2 (S.D. W. Va. Feb. 27, 2015) ("510(k) is not a 'relevant standard' here. Section 895.047 concerns whether a defect rendered the product 'unreasonably dangerous,' § 895.047(1), and, as the Supreme Court has held, 510(k) compliance does not go to the safety of a product."); *Williams v. Boston Sci. Corp.*, No. 2:12-CV-02052, 2016 WL 1448860, at *3 (S.D. W. Va. Apr. 12, 2016) (same). The Court continues to find these cases persuasive.[1]

Defendants argue that whether the presumption applies in this case, and whether Plaintiffs have overcome it, are questions of fact for the jury to decide. Doc. 12358 at 13 n.18. Defendants cite language from the Wisconsin model jury instruction, Wis JI-Civil § 3260.1, stating that the jury "must resolve this conflict." *Id.* But the "conflict" referred to is not whether the rebuttable presumption has arisen, but whether it has been overcome. *See* Doc. 12438 at 49 (quoting Wis JI-Civil § 3260.1 ("There was evidence received that at the time of sale, the product complied in material respects with relevant standards . . . adopted or approved by a federal or state law or agency. From this

[1] Defendants contend that it would be unfair for Plaintiffs to argue that Defendants are liable for negligence per se based on violations of the "safety" standards set forth in FDCA and its implementing regulations if Defendants are precluded from relying on the same standards for purposes of § 895.047(3)(b). Doc. 12358 at 13. This issue is moot because the Court has entered judgment in favor of Defendants on the negligence per se claim. Doc. 12589.

evidence, a rebuttable presumption arises that the product was not defective. However, there is also evidence which may be believed by you that the product is defective. You must resolve this conflict.")). Whether a defendant complied in material respects with the government standard may also create a triable issue of fact. *See Merryfield v. KLI, Inc.*, No. 17-C-742, 2018 WL 4178178, at *4 (E.D. Wis. Aug. 30, 2018) (denying summary judgment in part because the jury reasonably could find that the product was not made according to government specifications).

But whether the government standard is one from which a rebuttable presumption may arise in the first instance – that is, whether it is a "relevant" standard for purposes of § 895.047(3)(b) – is a question of law for the court. *See Williams*, 2016 WL 1448860, at *3 (finding as a matter of law that § 895.047(3)(b) creates no presumption of non-defectiveness for medical devices cleared under 510(k) review because that review does not concern the safety of the product); *Kilty*, 2018 WL 2464470, at *3 (finding that the presumption arose where the government issued specific safety regulations and certified the manufacture's compliance). Addressing that question of law, the Court again concludes that the 510(k) process, which looked at substantial equivalence rather than safety, and did not otherwise approve or certify the design of the Bard filter, is not a relevant standard for purposes of the presumption in § 895.047(3)(b). The Court will not instruct the jury that the presumption exists in this case.

IT IS ORDERED that Defendants' request for reconsideration (Doc. 12358 at 11-14) is **denied**.

Dated this 13th day of September, 2018.

David G. Campbell
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC **CASE MANAGEMENT ORDER NO. 38**

Following the close of evidence in the Hyde case, the Court conferred with the parties regarding scheduling matters. On the basis of the conference, the Court enters the following order.

I. Future Bellwether Trials.

The Court confirmed that it will hold two more bellwether trials in this MDL proceeding – Plaintiffs Mulkey and Tinlin. The Court will not hold a sixth bellwether trial. Because discovery in the Tinlin case is still being completed and Ms. Mulkey's health appears at this time to permit a trial, the Court will hold the Mulkey trial in February and the Tinlin trial in May. In the meantime, the Tinlin discovery schedule set forth in Doc. 12061, as modified by Doc. 12759, shall remain in place. The Court will rule as promptly as possible on the motion for summary judgment in the Mulkey case. If the Court grants summary judgment in Mulkey, the Tinlin trial will be held in February. If Ms. Mulkey's health worsens, the Court will hear from the parties on whether the Tinlin trial should be moved to February, but this issue should be raised with the Court

during the week of November 12, 2018, in light of the jury questionnaire schedule set forth below.

II. February Bellwether Trial.

A. Jury Questionnaire and Jury Selection.

1. By **November 26, 2018**, the parties shall provide the Court with proposed changes to the questionnaire used in the Hyde bellwether trial. The Court will consider these proposals in finalizing the questionnaire for the February trial.

2. The Clerk shall mail the questionnaire to 200 jurors no later than **November 30, 2018.** The questionnaire will instruct the prospective jurors to return it to the Court no later than **January 4, 2019**.

3. A thumb drive will be prepared for counsel (one for each side) containing copies of the questionnaires and will be available for pickup at the jury office on **January 11, 2019.** The thumb drive and any paper copies made by counsel must be returned to the Court by counsel on the day of jury selection.

4. On **January 18, 2019**, the Court will provide the parties with a list of prospective jurors the Court proposes to excuse for hardship on the basis of their responses to the first question in the questionnaire.

5. The Court will hold a final pretrial conference case on **January 28, 2019 at 10:00 a.m.** At the final pretrial conference, counsel will be permitted to challenge the Court's excusal of any of the listed jurors for hardship. If counsel do not object to the Court's proposed excusal of a particular juror for hardship, that juror will be excused from further involvement in this case. After hearing counsel's objections to hardship excusals, the Court will determine which of the challenged jurors should be excused for hardship and which should appear for voir dire. In addition, counsel shall be prepared to make challenges for cause to jurors on the basis of information contained in their questionnaires. These challenges should be limited to jurors who clearly could not serve as a fair juror on the basis of their questionnaire answers. The Court will rule on these challenges at the final pretrial conference. All

prospective jurors who returned questionnaires and who have not been excused for hardship or successfully challenged for cause will be candidates for voir dire.

6. On **February 11, 2019, at 9:00 a.m.,** 50 prospective jurors will be called to Court to appear for voir dire. The Court will permit counsel to ask follow-up questions of individual jurors based on information contained in the juror questionnaires. Counsel should not venture into new subjects – they should limit their follow-up questions to the items covered in the questionnaire. Following voir dire, the Court will hear and rule on challenges for cause.

7. The Court will seat 9 jurors. Each side will have 3 pre-emptory strikes.

8. The Court anticipates that opening statements and evidence trial will begin on the afternoon of **February 11, 2019**.

B. Dispositive and *Daubert* Motions.

Dispositive and *Daubert* motions in the Tinlin case shall be filed by **December 7, 2018,** responses by **December 21, 2018,** and replies by **December 28, 2019**. *See* Doc. 12061 ¶ 7.

C. Motions in Limine.

Motions in limine, limited to three pages each, shall be filed by **December 14, 2018**. Responses to motions in limine, limited to three pages each, shall be filed by **December 28, 2019**. No replies shall be filed.

D. Deposition Designations.

The parties shall provide deposition designations by **December 14, 2019**.

E. Final Pretrial Order.

The proposed final pretrial order shall be submitted by **January 11, 2019**. The Court will enter a separate order governing the materials that should be submitted with the final pretrial order.

F. Final Pretrial Conference.

The Court will hold a final pretrial conference on **January 28, 2019 at 10:00 a.m.**

G. Trial Days.

Trial in will be held on **February 11-15**, **19-22**, **25-28**, and **March 1, 2019**. Plaintiff will be allotted 33 hours of trial time and Defendants will be allotted 30 hours of trial time. This schedule should allow the case to get to the jury by the morning of February 28, 2019.

III. May Bellwether Trial.

A. Jury Questionnaire and Jury Selection.

1. By **March 1, 2019**, the parties shall provide the Court with proposed changes to the questionnaire. The Court will consider these proposals in finalizing the questionnaire.

2. The Clerk shall mail the questionnaire to 200 jurors no later than **March 8, 2019.** The questionnaire will instruct the prospective jurors to return it to the Court no later than **April 5, 2019**.

3. A thumb drive will be prepared for counsel (one for each side) containing copies of the questionnaires and will be available for pickup at the jury office on **April 12, 2019.** The thumb drive and any paper copies made by counsel must be returned to the Court by counsel on the day of jury selection.

4. On **April 19, 2019**, the Court will provide the parties with a list of prospective jurors the Court proposes to excuse for hardship on the basis of their responses to the first question in the questionnaire.

5. The Court will hold a final pretrial conference case on **April 30, 2019 at 10:00 a.m.** At the final pretrial conference, counsel will be permitted to challenge the Court's excusal of any of the listed jurors for hardship. If counsel do not object to the Court's proposed excusal of a particular juror for hardship, that juror will be excused from further involvement in this case. After hearing counsel's objections to hardship excusals, the Court will determine which of the challenged jurors should be excused for hardship and which should appear for voir dire. In addition, counsel shall be prepared to make challenges for cause to jurors on the basis of information contained in

their questionnaires. These challenges should be limited to jurors who clearly could not serve as a fair juror on the basis of their questionnaire answers. The Court will rule on these challenges at the final pretrial conference. All prospective jurors who returned questionnaires and who have not been excused for hardship or successfully challenged for cause will be candidates for voir dire.

6. On **May 13, 2019, at 9:00 a.m.,** 50 prospective jurors will be called to Court to appear for voir dire. The Court will permit counsel to ask follow-up questions of individual jurors based on information contained in the juror questionnaires. Counsel should not venture into new subjects – they should limit their follow-up questions to the items covered in the questionnaire. Following voir dire, the Court will hear and rule on challenges for cause.

7. The Court will seat 9 jurors. Each side will have 3 pre-emptory strikes.

8. The Court anticipates that opening statements and evidence will begin on the afternoon of **May 13, 2019**.

B. Dispositive and *Daubert* Motions.

Dispositive and *Daubert* motions shall be filed by **February 1, 2019,** responses by **March 1, 2019,** and replies by **March 15, 2019**.

C. Motions in Limine.

Motions in limine, limited to three pages each, shall be filed by **March 29, 2018**. Responses to motions in limine, limited to three pages each, shall be filed by **April 12, 2019**. No replies shall be filed.

D. Deposition Designations.

The parties shall provide deposition designations by **March 29, 2019**.

E. Final Pretrial Order.

The proposed final pretrial order shall be submitted by **April 12, 2019**. The Court will enter a separate order governing the materials that should be submitted with the final pretrial order.

F. Final Pretrial Conference.

The Court will hold a final pretrial conference on **April 30, 2019 at 10:00 a.m.**

G. Trial Days.

Trial will be held on **May 13-17**, **20-24**, **and 28-31**. Plaintiff will be allotted 33 hours of trial time and Defendants will be allotted 30 hours of trial time. This schedule should allow the case to get to the jury by the morning of May 30, 2019.

IV. Motion to Seal Trial Exhibits.

Defendants shall file any motion to seal trial exhibits in the Jones and Hyde cases by **October 26, 2018**.

V. Settlement Talks and Remand.

Counsel shall meet in person and engage in good faith global settlement talks no later than **November 30, 2018**. Within five working days after the talks, the parties shall file a joint report informing the Court that good faith settlement talks have been held and reporting generally on the outcome of such talks.

The Court intends to remand all cases in this MDL shortly after completion of the May 2019 bellwether trial.

VI. SNF Cases.

Defendants shall, by **November 2, 2018**, file a motion with the panel on multidistrict litigation to expand this MDL to include the SNF cases or to create a new MDL including the SNF cases. If the panel concludes that the motion should be granted in some respect, the undersigned judge will be willing to oversee the SNF cases.

Dated this 5th day of October, 2018.

David G. Campbell
United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC **CASE MANAGEMENT ORDER NO. 39 (Tinlin Bellwether Case)**

In Case Management Order ("CMO") No. 36, issued August 2, 2018, the Court set a schedule for the parties to follow in preparing the Tinlin bellwether case for trial. Doc. 12061. Certain of those deadlines were extended two months later. Doc. 12759. In CMO No. 38, the Court set a schedule for the final two bellwether trials, Mulkey and Tinlin, to be held in February and May 2019. Doc. 12853 at 2-6. The Court determined that Mulkey should be tried in February unless the Court were to grant summary judgment in the case or Ms. Mulkey's health were to worsen. *Id.* at 1-2. The Court left open the possibility that Tinlin could be tried in February instead of May. *Id.*

The parties have now filed a stipulation that Tinlin should be tried only in the May bellwether slot given that the present schedule for completion of discovery in Tinlin is not feasible. Docs. 12895, 12924. The parties propose an amended discovery schedule for Tinlin. *Id.*

The Court will accept the parties' stipulation that Tinlin should be tried in May and approve the proposed changes to the discovery schedule. This order will control the

schedule for the Tinlin trial. The deadlines and dates for the February bellwether trial, as set forth in CMO 38, will continue to apply to Mulkey. *See* Doc. 12538 at 2-4.

I. Tinlin Discovery Schedule.

The parties shall follow this amended schedule in preparing the Tinlin case for trial in May 2019:

1. The parties shall obtain updated medical records by **November 12, 2018**.

2. The parties shall complete the depositions of treating physicians and fact witnesses by **December 10, 2018**.

3. Plaintiff's case-specific expert disclosures shall be completed by **November 16, 2018**

4. Defendants' case-specific expert disclosures shall be completed by **December 17, 2018**.

5. Case-specific experts shall be deposed by **January 18, 2019**.

II. Tinlin Trial Schedule.

A. Jury Questionnaire and Jury Selection.

1. By **March 1, 2019**, the parties shall provide the Court with proposed changes to the questionnaire. The Court will consider these proposals in finalizing the questionnaire.

2. The Clerk shall mail the questionnaire to 200 jurors no later than **March 8, 2019.** The questionnaire will instruct the prospective jurors to return it to the Court no later than **April 5, 2019**.

3. A thumb drive will be prepared for counsel (one for each side) containing copies of the questionnaires and will be available for pickup at the jury office on **April 12, 2019.** The thumb drive and any paper copies made by counsel must be returned to the Court by counsel on the day of jury selection.

4. On **April 19, 2019**, the Court will provide the parties with a list of prospective jurors the Court proposes to excuse for hardship on the basis of their

responses to the first question in the questionnaire.

5. The Court will hold a final pretrial conference on **April 30, 2019 at 10:00 a.m.** At the final pretrial conference, counsel will be permitted to challenge the Court's excusal of any of the listed jurors for hardship. If counsel do not object to the Court's proposed excusal of a particular juror for hardship, that juror will be excused from further involvement in this case. After hearing counsel's objections to hardship excusals, the Court will determine which of the challenged jurors should be excused for hardship and which should appear for voir dire. In addition, counsel shall be prepared to make challenges for cause to jurors on the basis of information contained in their questionnaires. These challenges should be limited to jurors who clearly could not serve as a fair juror on the basis of their questionnaire answers. The Court will rule on these challenges at the final pretrial conference. All prospective jurors who returned questionnaires and who have not been excused for hardship or successfully challenged for cause will be candidates for voir dire.

6. On **May 13, 2019, at 9:00 a.m.,** 50 prospective jurors will be called to Court to appear for voir dire. The Court will permit counsel to ask follow-up questions of individual jurors based on information contained in the juror questionnaires. Counsel should not venture into new subjects – they should limit their follow-up questions to the items covered in the questionnaire. Following voir dire, the Court will hear and rule on challenges for cause.

7. The Court will seat 9 jurors. Each side will have 3 pre-emptory strikes.

8. The Court anticipates that opening statements and evidence will begin on the afternoon of **May 13, 2019**.

B. Dispositive and *Daubert* Motions.

Dispositive and *Daubert* motions shall be filed by **February 1, 2019,** responses by **March 1, 2019,** and replies by **March 15, 2019**.

C. Motions in Limine.

Motions in limine, limited to three pages each, shall be filed by **March 29, 2018**. Responses to motions in limine, limited to three pages each, shall be filed by **April 12, 2019**. No replies shall be filed.

D. Deposition Designations.

The parties shall provide deposition designations by **March 29, 2019**.

E. Final Pretrial Order.

The proposed final pretrial order shall be submitted by **April 12, 2019**. The Court will enter a separate order governing the materials that should be submitted with the final pretrial order.

F. Final Pretrial Conference.

The Court will hold a final pretrial conference on **April 30, 2019 at 10:00 a.m.**

G. Trial Days.

Trial will be held on **May 13-17**, **20-24**, **and 28-31**. Plaintiff will be allotted 33 hours of trial time and Defendants will be allotted 30 hours of trial time. This schedule should allow the case to get to the jury by the morning of May 30, 2019.

Dated this 16th day of October, 2018.

David G. Campbell
Senior United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL15-2641-PHX-DGC
Debra and James Tinlin, a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV16-0263-PHX-DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters. The MDL Plaintiffs received implants of Bard IVC filters and claim they are defective and have caused serious injury or death.

One of the MDL cases is brought by Plaintiff Debra Tinlin. She received a Bard filter fourteen years ago. Her case has been chosen as one of several bellwether cases and is set for trial in May 2019. Defendants have filed a motion for summary judgment. Doc. 15071. The motion is fully briefed. Docs. 15696, 16011. The parties request oral argument, but it will not aid the Court's decision. *See* Fed. R. Civ. P. 78(b); LRCiv

7.2(f). For reasons stated below, the Court will grant the motion in part and deny it in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. An IVC filter is a device implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves multiple versions of Bard IVC filters – the Recovery, G2, G2X, Eclipse, Meridian, and Denali. They are spider-shaped devices that have multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with elastic hooks that attach to the IVC wall, and bent arms to catch or break up blood clots.

The MDL Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have higher risks of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs further allege that Bard failed to warn patients and physicians about these higher risks. Defendants dispute these allegations, contending that Bard filters are safe and effective, that their complication rates are low and comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters.

II. The Tinlin Plaintiffs.

Plaintiff Debra Tinlin has a history of deep vein thrombosis and pulmonary emboli. She received a Bard Recovery filter on May 7, 2005. Dr. Joshua Riebe implanted the filter.

On June 10, 2013, Ms. Tinlin experienced cardiac tamponade after the filter fractured and two struts embolized in the right ventricle of her heart. She had emergency surgery to drain a pericardial effusion. No fractured strut was found during the procedure. She was discharged ten days later.

On July 31, 2013, a fractured strut was removed through open heart surgery. A chest scan showed several other struts perforating the IVC wall. Subsequent scans revealed multiple fractured struts in the pulmonary arteries. These struts and the filter have not been removed.

Ms. Tinlin and her husband assert various claims against Bard under Wisconsin law, some of which have been withdrawn.[1] The following claims remain: failure to warn (Counts II and VII), design defect (Counts III and IV), misrepresentation (Counts VIII and XII), concealment (Count XIII), deceptive trade practices (Count XIV), and loss of consortium (Count XV). *See* Doc. 364 (master complaint); Doc. 1, Case No. CV-16-00263 (short-form complaint).[2]

Defendants seek summary judgment on the remaining claims and future damages, but not on Plaintiff's request for punitive damages. Doc. 15071 at 2-4. The Court will grant summary judgment on the misrepresentation and deceptive trade practices claims, deny summary judgment on the claims for failure to warn, design defect, concealment, and loss of consortium, and grant summary judgment in part with respect to future damages.

III. Summary Judgment Standard.

A party seeking summary judgment "bears the initial responsibility of informing the court of the basis for its motion and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is warranted where the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Summary judgment is also appropriate against a party who "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322.

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[1] The parties agree that Wisconsin law governs the Tinlins' claims. Doc. 15071 at 3 n.1.

[2] The master complaint is the operative pleading in this MDL. It gives notice, pursuant to Rule 8, of the allegations that Plaintiffs assert generally. Plaintiff-specific allegations are contained in individual short-form complaints and fact sheets. *See* Doc. 249 at 6. The master complaint asserts seventeen claims and seeks both compensatory and punitive damages. Doc. 364 ¶¶ 166-349. The Tinlins do not assert wrongful death or survival claims (Counts XVI and XVII), and have withdrawn claims for manufacturing defect (Counts I and V), failure to recall (Count VI), negligence per se (Count IX), and breach of warranty (Counts X and XI). *See* Doc. 15071 at 2.

Only disputes over facts that might affect the outcome of the suit will preclude summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence must be viewed in the light most favorable to the nonmoving party, and all justifiable inferences are drawn in that party's favor because "[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions[.]" *Id.* at 255; *see Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)

III. Failure to Warn Claims (Counts II and VII).

Plaintiffs assert strict liability and negligent failure to warn claims. *See* Doc. 364 ¶¶ 171-81, 210-17; Doc. 1 at 3, Case No. CV-16-00263. To establish each claim, Plaintiffs must show, among other things, that the lack of an adequate warning was a cause of their injuries. *See* Wis. Stat. § 895.047(1)(e) (a plaintiff asserting a strict liability claim must prove that "the defective condition was a cause" of her injuries); *Kessel v. Stansfield Vending, Inc.*, 714 N.W.2d 206, 211 (Wis. Ct. App. 2006) (a plaintiff claiming negligent failure to warn must prove a "causal connection between the defendant's breach of the duty of care and the plaintiff's injury"). "Under Wisconsin law, negligence or defect 'caused' an injury if it was a substantial factor in producing the injury." *Burton v. Am. Cyanamid*, No. 07-CV-0303, 2019 WL 325318, at *2 (E.D. Wis. Jan. 25, 2019); *see Sumnicht v. Toyota Motor Sales, U.S.A.*, 360 N.W.2d 2, 11 (Wis. 1984) ("The long-standing test for cause in Wisconsin is whether the defect was a substantial factor in producing the injury."); *Morgan v. Pa. Gen. Ins.*, 275 N.W.2d 660, 666 (Wis. 1979) ("The test of cause-in-fact is whether the negligence was a 'substantial factor' in producing the injury."); *Fandrey v. Am. Family Mut. Ins.*, 680 N.W.2d 345, 353 (Wis. 2004) ("When Wisconsin courts currently speak of 'cause,' they do so in the context of the substantial factor test for cause-in-fact."); *see also* Wis JI-Civil 1500 (general causation standard).

Defendants contend that the failure to warn claims fail because Plaintiffs cannot show that an adequate warning would have changed Dr. Riebe's decision to use a Recovery filter for Ms. Tinlin. Doc. 15071 at 3, 7-9. The Court does not agree.[3]

Defendants note that Dr. Riebe does not recall seeing the Recovery's instructions for use ("IFU") and does not routinely read IFUs or "dear doctor" letters. Doc. 15071 at 8-9. But "it does not follow that he would have ignored any warnings provided by [D]efendants." *Stevens v. Stryker Corp.*, No. 12-CV-63-BBC, 2013 WL 12109101, at *6 (W.D. Wis. May 9, 2013). Defendants do not contend that IFUs and "dear doctor" letters are the only avenues by which Bard can provide warnings to physicians. *See* Doc. 15071 at 9. Dr. Riebe testified that sales representatives for IVC filter manufacturers, including Bard, visited the hospital where he performed surgery and called on him as a customer throughout his practice. Doc. 15702 ¶ 10; *see* Doc. 15702-1 at 3, 10. Because Bard sales representatives could have personally provided warnings about the Recovery to Dr. Riebe, the fact that he did not read IFUs or "dear doctor" letters does not establish a lack of causation.

Dr. Riebe testified that he needed complete and accurate information from medical device manufacturers to help him conduct a proper risk-benefit analysis. Doc. 15702-1 at 5. He stated that he would have wanted to know about the Recovery's alleged higher risks of failure, and that Bard did not understand the root causes, did not have a good

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[3] Defendants assert that they had a duty to warn Dr. Riebe, and not Ms. Tinlin directly, under the learned intermediary doctrine. *Id.* at 7-8. The Wisconsin Supreme Court has not decided whether to adopt the doctrine, and federal courts applying Wisconsin law are split on the issue. *See* Doc. 12007 at 14 n.6 (discussing the conflicting case law). The Court need not decide the issue on the present motion because summary judgment is not warranted on the failure to warn claims even under the learned intermediary doctrine. *See Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968 (E.D. Wis. 2009) (because a triable issue existed as to whether the defendant adequately warned the prescribing physician about the drug's risks, "the 'learned intermediary' doctrine would not preclude any 'failure to warn' claim, even if the court determined that the doctrine applied"). Defendants argue in their reply that Plaintiffs cannot prove causation if the duty to warn is owed to Ms. Tinlin (Doc. 16011 at 3-4), but the Court will not grant summary judgment based on an argument raised for the first time in a reply brief. *See Zamani v. Carnes*, 491 F.3d 990, 997 (9th Cir. 2007).

understanding of the long-term performance of its retrievable filters or the dynamics of the IVC, had placed the Recovery on hold due to migration problems, and internally found the Recovery to have unacceptable risks. *Id.* at 6-8, 14. This information would have been important for understanding the Recovery's safety and conducting a proper risk-benefit analysis. *Id.* at 8-9, 19; *see* Doc. 15701 ¶¶ 17-22. Bard's knowledge that overweight patients tend to have large expansions of their IVCs, if shared with Dr. Riebe, would have helped him select a filter that would have remained in place in Ms. Tinlin. Doc. 15702-1 at 22; *see* Doc. 15702 ¶ 5.

A jury reasonably could infer from this evidence that Bard's failure to warn Dr. Riebe about the Recovery's higher risks of failure, Bard's lack of knowledge about the root causes, and the Recovery's known migration problems in overweight patients was a substantial factor in Dr. Riebe's decision to choose a Recovery for Ms. Tinlin. *See Burton v. Am. Cyanamid*, 334 F. Supp. 3d 949, 967 (E.D. Wis. 2018) (denying summary judgment where the jury could draw "the permissible inference . . . that the persons responsible for selecting [the product] would have heeded warnings regarding the risk . . . if such warnings had been issued"); *Stevens*, 2013 WL 12109101, at *6 (finding a triable issue with respect to causation even though the physician generally did not rely on information he received from the defendants when he decided to use their medical device); *Forst*, 602 F. Supp. 2d at 969 (a jury could rely on the prescribing physician's testimony that the lack of warning about the drug's increased risk for suicide prevented him from doing a proper risk-benefit analysis in concluding that his decision to prescribe would have changed); *Michaels v. Mr. Heater, Inc.*, 411 F. Supp. 992, 1007 (W.D. Wis. 2006) (denying summary judgment where the jury reasonably could find that the failure to provide adequate warnings was a substantial factor in causing the plaintiff's injuries).[4]

[4] Defendants object to Dr. Riebe's testimony that he would have wanted to know certain information about the Recovery, claiming that the testimony lacks foundation and the questions are incomplete hypotheticals. Doc. 16011 at 5 n.5. But Defendants do not provide a basis for the objections. Dr. Riebe clearly is qualified to testify about information he would want to know from IVC filter manufacturers in order to conduct a proper risk-benefit analysis. Defendants have not shown that this testimony should be disregarded at the summary judgment stage. *See Quanta Indemnity Co. v. Amberwood*

Defendants contend that because Dr. Riebe had no involvement in selecting the IVC filters used at his hospital, and never suggested that any filter other than a Recovery could have been used for Ms. Tinlin, no reasonable inference can be drawn that he would have selected a different filter regardless of what warning Bard provided. Doc. 15071 at 9. But Dr. Riebe testified that he often would switch to a Cook Bird's Nest filter for patients with large IVCs. Doc. 15702-1 at 25; *see* Doc. 15702 ¶ 5.

Defendants have not shown, as a matter of undisputed fact, that their alleged failure to warn was not a cause of Plaintiffs' injuries. The Court will deny summary judgment on the failure to warn claims.[5]

IV. Misrepresentation Claims (Counts VIII and XII).

Wisconsin common law recognizes three distinct claims of misrepresentation: negligent, strict liability, and intentional or fraudulent. *See Van Den Heuvel v. AI Credit Corp.*, 951 F. Supp. 2d 1064, 1073 (E.D. Wis. 2013) (citing *Ollerman v. O'Rourke Co., Inc.*, 288 N.W.2d 95, 99 (Wis. 1980)); *see also Kaloti Enters, Inc. v. Kellogg Sales Co.*, 699 N.W.2d 205, 211 (Wis. 2005) (noting that "intentional misrepresentation [is] sometimes referred to as fraudulent misrepresentation"). Each claim requires the plaintiff to show that she relied to her detriment on a false representation of fact. *See Van Den Heuvel*, 951 F. Supp. 2d at 1073; *Blenker Bldg. Sys., Inc. v. Array Fin. Servs.*, 340 F. Supp. 3d 792, 797-98 (W.D. Wis. 2018); *Novell v. Migliaccio*, 749 N.W.2d 544, 553

Dev. Inc., No. CV 11-1807-PHX-JAT, 2014 WL 1246144, at *2 (D. Ariz. March 26, 2014) (material that could be presented in a form admissible at trial may be used to avoid summary judgment).

[5] Defendants assert that any failure to warn was not the "proximate cause" of Plaintiffs' injuries. Docs. 15071 at 7, 16011 at 5. But the use of "proximate cause" to describe the extent of liability based on lack of causal connection "has long since been abandoned in Wisconsin in favor of the 'substantial factor' test used to establish cause-in-fact, which is a jury issue." *Fandrey*, 680 N.W.2d at 353 (citations omitted); *see Michaels*, 411 F. Supp. at 1006 (noting that "proximate cause" is "a legal theory that Wisconsin no longer uses to discuss the causal connection between wrongdoing and injury"). Under current Wisconsin law, "proximate cause" is "simply short hand for the public policies a court may consider to deny recovery even if the plaintiff proves cause-in-fact." *Stevens*, 2013 WL 12109101, at *6. Defendants identify no such public policies.

(Wis. 2008); *Tietsworth v. Harley-Davidson, Inc.*, 677 N.W.2d 233, 239 (Wis. 2004); *Whipp v. Iverson*, 168 N.W .2d 201, 203-204 (Wis. 1969); *see also* Wis JI-Civil 2400.

Plaintiffs assert negligent and fraudulent misrepresentation claims. *See* Doc. 364 ¶¶ 218-28, 245-59; Doc. 1 at 3, Case No. CV-16-00263. Defendants argue that the claims fail because Plaintiffs cannot show that Ms. Tinlin or Dr. Riebe relied on any Bard representation in selecting a Recovery filter. Doc. 15071 at 9-10. The Court agrees.

Plaintiffs assert that a Bard sales representative may have met with Dr. Riebe in the past. Doc. 15696 at 7 (citing Doc. 15702 ¶ 10). But even if this were true, Plaintiffs present no evidence that the sales representative made representations on which Dr. Riebe relied in selecting a Recovery for Ms. Tinlin. Absent such evidence, Plaintiffs cannot establish their misrepresentation claims. *See Blenker Bldg. Sys.*, 340 F. Supp. 3d at 798 (noting that "reliance is an element of all common law misrepresentation claims") (citing *Novell*, 749 N.W.2d at 553); *Kimberly Area Sch. Dist. v. Zdanovec*, 586 N.W.2d 41, 51 (Wis. Ct. App. 1998) (the element of reliance is "common to all types of misrepresentation").

Plaintiffs assert that Dr. Riebe relied on risk-benefit information from those who trained him. Doc. 15696 at 7. Dr. Riebe was trained by Dr. John McDermott, an interventional radiologist at the University of Wisconsin. *Id.* Plaintiffs claim that Dr. McDermott was involved in a 2004 email with Bard employees that downplayed concerns about the number of Recovery migrations in bariatric patients. *Id.*; *see* Doc. 15702-1 at 23. From this evidence, Plaintiffs contend, "[i]t is more than reasonable to infer that Bard's actions caused Dr. Riebe's use of the Recovery filter and Ms. Tinlin's injuries." Doc. 15696 at 7.

But Plaintiffs present no evidence that misleading statements about Recovery migration problems were shared with Dr. Riebe, or that he relied on any such statements in selecting a Recovery for Ms. Tinlin. Moreover, it appears that the "John McDermott"

involved in the email is the former president of Bard Peripheral Vascular, and not the physician who trained Dr. Riebe at the University of Wisconsin. *See* Doc. 16011 at 6-7.[6]

Reliance is an essential element of Plaintiff's common law misrepresentation claims. *See Blenker Bldg. Sys.*, 340 F. Supp. 3d at 798; *Kimberly Area Sch. Dist.*, 586 N.W.2d at 51. Plaintiffs have failed to make a showing sufficient to establish the existence of this element. The Court will grant summary judgment on the negligent and fraudulent misrepresentation claims. *See Celotex*, 477 U.S. at 322; *Valente v. Sofamor, S.N.C.*, 48 F. Supp. 2d 862, 877 (E.D. Wis. 1999) (granting summary judgment where "the plaintiffs [did] not present evidence to show that they or their doctors relied on the defendants' alleged misrepresentations regarding the efficacy and safety of [their] pedicle screw device"); *Staudt v. Artifex Ltd.*, 16 F. Supp. 2d 1023, 1031 (E.D. Wis. 1998) (granting summary judgment where the plaintiff failed to point to any evidence that he relied on the defendants' misrepresentations about their spinal devices); *Collins v. Eli Lilly Co.*, 342 N.W.2d 37, 54 (Wis. 1984) (granting summary judgment on a misrepresentation claim because "[e]ven assuming that the defendants made misrepresentations concerning [their drug], since there was no reliance on those misrepresentations, there can be no recovery under this cause of action").

V. Concealment Claim (Count XIII).

A defendant is liable for fraudulent concealment in Wisconsin "when, having a duty to disclose, he intentionally fails to do so with the intent to deceive the plaintiff and thereby induces the plaintiff to act to his or her detriment." *Schmidt v. Bassett Furniture Indus.*, No. 08-C-1035, 2009 WL 3380354, at *10 (E.D. Wis. Oct. 20, 2009) (citing *Kaloti Enters.*, 699 N.W.2d at 211-12); *see Ollerman*, 288 N.W.2d at 100 (noting that the "failure to disclose [a] fact is treated in the law as equivalent to a representation of the

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[6] In the email, McDermott wrote to various high-level Bard employees that "*we* have had several discussions with physicians about bariatric patients and I've asked *our Filter team* to summarize what we know to date." Doc. 15702-2 at 2 (emphasis added). He further stated that he would provide a "summary of *our filter complaints [and] shipments*." *Id.* A copy of the email provided by Defendants shows McDermott's email address as "John.McDermott@crbard.com." Doc. 16011-1 at 2.

non-existence of the fact."). Plaintiffs allege that Defendants failed to disclose, among other things, that Bard filters had higher risks of complications than other IVC filters. *See* Doc. 364 ¶¶ 261-62.

Defendants contend that there is no evidence showing that Bard's alleged concealment of adverse information about the Recovery caused Plaintiffs' injuries. Doc. 15071 at 10. But as explained above, Dr. Riebe testified that he expected Bard to warn him about the Recovery's higher risks of complications. *See* Docs. 15701 ¶¶ 17-22, 15702-1 at 5-9, 12-19. He explained that a manufacturer's concealment of true risks prevents him from conducting a proper risk-benefit analysis. Doc. 15702-1 at 5. A jury reasonably could conclude from this evidence that Bard's failure to disclose the Recovery's true risks was a cause of Dr. Riebe's decision to use the device for Ms. Tinlin, and her resulting injuries. The Court will deny summary judgment on the concealment claim.

VI. Deceptive Trade Practices Act Claim (Count XIV).

Plaintiffs assert a violation of Wisconsin's Deceptive Trade Practices Act, Wis. Stat. § 100.18. *See* Doc. 364 ¶ 321; Doc. 1 at 4, Case No. CV-16-00263. The statute prohibits sellers from making, with the intent to induce the public to enter into an obligation relating to the purchase of goods, any representation that is untrue, deceptive, or misleading. § 100.18(1). The statute provides a private right of action for "[a]ny person suffering pecuniary loss because of a violation[.]" § 100.18(11)(b)(2). "[T]here are three elements in a § 100.18 cause of action: (1) the defendant made a representation to the public with the intent to induce an obligation, (2) the representation was 'untrue, deceptive or misleading,' and (3) the representation materially induced (caused) a pecuniary loss to the plaintiff." *Novell*, 749 N.W.2d at 553 (citing *K & S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 732 N.W.2d 792, 798 (Wis. 2007)); *see Skyrise Constr. Grp. v. Annex Constr., LLC*, No. 18-CV-381, 2019 WL 699964, at *6 (E.D. Wis. Feb. 20, 2019); Wis JI-Civil 2418.

Defendants argue that Plaintiffs' § 100.18 claim fails for lack of causation. Doc. 15071 at 10. Plaintiffs do not dispute that causation is an essential element of such a claim. *See* Doc. 15696 at 8 (citing *Andersen v. Vavreck*, No. 15-CV-667-PP, 2017 WL 680424, at *3 (E.D. Wis. Feb. 21, 2017) (a plaintiff asserting a violation of § 100.18 must show that "the representation caused him to suffer a pecuniary loss")). Rather, Plaintiffs cite *Novell* for the proposition that a § 100.18 claim requires no element of reliance. *Id.*

But the question in *Novell* was "whether *reasonable* reliance is a necessary element in a § 100.18 claim." 749 N.W.2d at 551 (emphasis in original). The *Novell* court made clear that although reasonable reliance is not an element, "[r]eliance is an aspect of the third element, whether a representation *caused* the plaintiff's pecuniary loss." 749 N.W.2d at 553 (emphasis added); *see Ramsden v. Farm Credit Servs. of N. Cent. Wis. ACA*, 590 N.W.2d 1 (Wis. Ct. App.1998) (noting that reliance in a misrepresentation claim is equivalent to the causation element in a traditional negligence claim). Wisconsin district courts have read *Novell* "to mean that satisfying the element of causation for a claim under § 100.18 requires more than a showing by the plaintiff that it sustained a loss that is somehow connected to a misrepresentation made to 'the public.'" *Grice Eng'g, Inc. v. JG Innovations, Inc.*, 691 F. Supp. 2d 915, 923 (W.D. Wis. 2010) (citing *Spacesaver Corp. v. Marvel Grp., Inc.*, 621 F. Supp. 2d 659, 663 (W.D. Wis. 2009)). Rather, "the question is whether 'the representation materially induced the plaintiff's decision to act and whether the plaintiff would have acted in the absence of the representation.'" *Id.* (quoting *Novell*, 749 N.W.2d at 554; alterations omitted); *see also Tim Torres Enters. v. Linscott*, 416 N.W.2d 670, 675 (Wis. Ct. App. 1987) (interpreting § 100.18 "as requiring some proof beyond the content of the advertisement itself to establish that the plaintiff was in fact damaged by it"); Wis JI-Civil 2418 (in determining whether the plaintiff's loss was caused by the defendant's representation, "the test is whether [the plaintiff] would have acted in its absence").

Plaintiffs assert that the record is replete with examples of Bard's misleading statements to the public. Doc. 15696 at 9. But Plaintiffs present no evidence showing

that the statements materially induced Ms. Tinlin or Dr. Riebe to select a Recovery filter, or that a different filter would have been selected in the absence of the statements. Without such evidence, Plaintiffs cannot show that the statements caused them to suffer a pecuniary loss. The Court will grant summary judgment on the § 100.18 claim. *See Valente*, 48 F. Supp. 2d at 874 (granting summary judgment where "the plaintiffs [did] not show that they or their doctors relied on the defendants' allegedly fraudulent representations when they elected to undergo spinal fusion surgery [and therefore could] not show a causal connection between the defendants' alleged conduct and any pecuniary loss suffered as a result of their continued back pain"); *Monson v. Acromed Corp.*, No. 96-C-1336, 1999 WL 1133273, at *24 (E.D. Wis. May 12, 1999) (finding summary judgment warranted regardless of whether reliance is an element of a § 100.18 claim because the record was devoid of evidence showing a causal connection between the defendants' statements and the plaintiff's loss); *Andersen*, 2017 WL 680424, at *3 (granting summary judgment where the plaintiff "failed to make a sufficient showing that his damages were caused by the defendants' conduct").

VII. Design Defect Claims (Counts III and IV).

Plaintiffs assert strict liability and negligent design defect claims. *See* Doc. 364 ¶¶ 182-97; Doc. 1 at 3, Case No. CV-16-00263. Defendants contend that each claim fails because Plaintiffs offer no reasonable alternative design for the Recovery. Doc. 15071 at 10-13. The Court does not agree.[7]

Defendants do not dispute that Plaintiffs' engineering expert, Dr. Robert McMeeking, offers several alternative designs to the Recovery that he believes would

[7] Wisconsin's strict liability statute, Wis. Stat. § 895.047, expressly requires evidence of a reasonable alternative design to show that a product is defective. § 895.047(1)(a); *see also Janusz v. Symmetry Med. Inc.*, 256 F. Supp. 3d 995, 1000 (E.D. Wis. 2017); Wis JI-Civil 3260.1. Defendants contend that such evidence is also required to establish a negligent design claim. Doc. 15071 at 10-11 (citing *Below v. Yokohama Tire Corp.*, No. 15-CV-529-WMC, 2017 WL 679153, at *3 (W.D. Wis. Feb. 21, 2017) (noting that "the two theories are similar . . . because the reasonableness of a product's design turns essentially on whether the seller could have come up with a less dangerous design")). The Court need not decide the issue for purposes of summary judgment because Plaintiffs have presented sufficient evidence of a reasonable alternative design.

have helped reduce the risk of the failures that occurred in Ms. Tinlin's filter. Doc. 15071 at 11. Specifically, Dr. McMeeking opines that "reasonable alternative designs and alternative features available to Bard before Ms. Tinlin received her filter include . . . caudal anchors, penetration limiters, two-tier design, and a better (smoother and rounded) chamfer at the mouth of the 'cap' on the filter." Doc. 15073 ¶ 21; *see* Doc. 15074-3 at 3. Dr. McMeeking explains that "[m]any of these design features existed in other IVC filter products already on the market, including the Simon Nitinol Filter, the Cook Gunther Tulip filter, the Greenfield filter, and the Cook Bird's Nest filter." Doc. 15701 ¶ 30; *see* Doc. 15071-8 at 4. A jury reasonably could find from this evidence that specific and reasonable alternative design changes were available when Defendants developed the Recovery. *See Rogers v. K2 Sports, LLC*, 348 F. Supp. 3d 892, 902-03 (W.D. Wis. 2018) (denying summary judgment where the plaintiff's expert opined that the helmet in question did not provide sufficient protection due to a tapered edge while other helmets without tapering provided the necessary protection); *see also* Docs. 12007 at 13, 12805 at 5-6 (finding in the Hyde case that Dr. McMeeking's opinions constituted sufficient evidence that reasonable alternative designs were available to Bard when it developed the G2X and Eclipse filters).[8]

Defendants contend that permanent IVC filters, such as the Simon Nitinol filter ("SNF"), are not reasonable alternative designs for the retrievable Recovery. Doc. 15071 at 11-13. But the Recovery was designed and cleared for permanent use (Doc. 7950 ¶¶ 8, 17), and Plaintiffs have presented evidence that Ms. Tinlin's filter remains implanted as a permanent device (Doc. 15701 ¶¶ 23-24). Whether the retrievability of the Recovery makes it sufficiently unlike the SNF and other permanent filters to disqualify them as reasonable alternative designs is a question for the jury to decide. *See* Doc. 12805 at 6.[9]

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[8] Defendants note that summary judgment would be warranted if their motions to exclude Dr. McMeeking's opinions are granted (Doc. 15071 at 11), but the motions were denied in relevant respects (Doc. 16992).

[9] Defendants' reliance on *Oden v. Boston Scientific Corp.*, 2018 U.S. Dist. LEXIS

Defendants further contend that the Cook filters and Bard's later-generation filters are not reasonable alternative designs because Dr. McMeeking believes they are defective. Doc. 15071 at 13. Defendants cite *Tunnel v. Ford Motor Co.*, 385 F. Supp. 2d 582 (W.D. Va. 2005), which found that Virginia requires a showing that "the proposed alternative would truly cure a product of its alleged defects[.]" 385 F. Supp. 2d at 586. But a manufacturer may be liable under Wisconsin's product liability statute where the alternative design would have "reduced" the harm posed by the product. Wis. Stat. § 895.047(1)(a); *see* Doc. 12007 at 13. Defendants do not dispute that specific alternative design features identified by Dr. McMeeking – caudal anchors, penetration limiters, and a chamfered cap – help reduce the risk of filter failures like those experienced by Ms. Tinlin.[10]

Plaintiffs have presented sufficient evidence of a reasonable alternative design. The Court will deny summary judgment on the design defect claims. *See Rogers*, 348 F. Supp. 3d at 902-03.[11]

VIII. Future Damages.

Wisconsin law holds that future injuries and healthcare must be established by a medical probability. *See Pucci v. Rausch*, 187 N.W.2d 138, 142 (Wis. 1971) (citing cases). "But medical probability does not mean absolute certainty or metaphysical certainty." *Reyes v. Greatway Ins.*, 582 N.W.2d 480, 485 (Wis. Ct. App. 1998). As long

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102639 (E.D.N.Y. June 4, 2018), is misplaced because the case involved the granting of a motion to dismiss where the plaintiff had received a permanent filter and alleged that retrievable filters were not designed to be permanent. *Id.* at *12-13. Although Dr. Riebe found Ms. Tinlin to be a candidate for a retrievable filter (Doc. 15073 ¶ 5), the Recovery also can serve as a permanent device (*see* Docs. 7950 ¶¶ 8, 15701 ¶ 24).

[10] Defendants note in their reply that Dr. McMeeking agrees that his proposed design changes may not have "avoided" Ms. Tinlin's injuries. Doc. 16011 at 8. But as explained above, it is sufficient that the alternative design would have "reduced" the risk of harm. Wis. Stat. § 895.047(1)(a).

[11] Given this ruling and the denial of summary judgment on the claims for failure to warn and concealment, Mr. Tinlin's claim for loss of consortium (Count XV) survives summary judgment. *See* Doc. 15071 at 3, 14; *Finnegan v. Wis. Patients Comp. Fund*, 666 N.W.2d 797, 805 (Wis. 2003) ("[A] derivative claim for loss of consortium or loss of society and companionship does not have its own elements distinct from the negligence claim to which it attaches[.]") (citing Wis JI-Civil 1815).

as an expert's opinion is based on probability, and not mere possibility or conjecture, the opinion is sufficient to support an award of future damages. *Weber v. White*, 681 N.W.2d 137, 143 (Wis. 2004). Defendants contend that Plaintiffs' medical experts could not opine that Ms. Tinlin "probably" will have future complications and medical expenses from her Recovery filter. Doc. 15071 at 14-15.

A. Dr. Derek Muehrcke.

Dr. Muehrcke testified that he believes Ms. Tinlin is at future risk for various complications from her Recovery filter because the filter disintegrated, sending multiple fragments to the heart and lungs, and the filter remains unstable with several missing arms. Doc. 15702-4 at 7-8. He opines that Ms. Tinlin's risk of future complications is 40 percent at five and half years. Doc. 15704-5 at 8. He holds these opinions to a reasonable degree of medical probability. Doc. 15702-4 at 8.

Dr. Muehrcke's opinions are expressed "not in terms of 'possibilities' but 'probabilities[.]'" *Bleyer*, 120 N.W.2d at 160. The opinions therefore are sufficient to support a jury finding that Ms. Tinlin probably will suffer future injuries from the Recovery which will require further medical treatment. *See id.*; *Weber*, 681 N.W.2d at 143 (noting that Wisconsin law "does not require mathematical certainty" to establish future medical care and finding the expert's estimate that the plaintiff's future care would "probably be around 20 to 25 visits a year . . . on an average" sufficient to support an award of future chiropractic expenses); *Reyes*, 582 N.W.2d at 485 (finding that the "doctor's use of the term 'significant chance' indicates an opinion to a reasonable degree of medical probability"); *Pucci*, 187 N.W.2d at 142 (noting that opinions expressed in terms of "I feel" or "I believe" have been held to be sufficient) (citing *Hintz v. Mielke*, 112 N.W.2d 720, 725 (Wis. 1961)). The Court will deny summary judgment with respect to the future injuries and medical care opined to by Dr. Muehrcke.[12]

[12] Defendants note that Dr. Muehrcke did not perform a differential diagnosis for Ms. Tinlin's shortness of breath, but make no argument as to why this warrants summary judgment. Doc. 15071 at 14.

B. Dr. Darren Hurst.

Defendants assert that Dr. Hurst could not opine that Ms. Tinlin probably will experience pneumothorax, abscess, and lung hemorrhage in the future. Doc. 15071 at 15 (citing Doc. 15073 ¶¶ 34-35). Defendants contend that the monitoring and medical intervention costs that Dr. Hurst recommends for these conditions should not be compensable, but specifically identify only the costs for lung resection and life-long CT scans. *Id.*

1. Lung Resection.

Dr. Hurst states in his report that three filter arms embolized in Ms. Tinlin's right lung, but makes clear that "the future behavior and possible morbidity and mortality of these embolized arms *is currently unknown*." Doc. 15074-6 at 3 (emphasis added). He further states that filter fragments in the lungs of other patients have resulted in pneumothorax, abscess, and lung hemorrhage, and the filter arms in Ms. Tinlin's lung will require lung resection for removal "if they become symptomatic[.]" *Id.* But Dr. Hurst does not know whether it is probable that the filter arms will cause pneumothorax, abscess, or lung hemorrhage. He testified that "[f]or all of these potential complications, there's no data," there "are only case reports of similar types of objects in the lungs that have caused these problems," and "[n]o one has done a long-term study because it is so new." Doc. 15074-7 at 7.

This testimony shows that the risk of future complications from the filter arms in Ms. Tinlin's lung is a mere possibility, and "an expert opinion expressed in terms of a 'mere possibility' is insufficient to sustain a finding" of future damages. *Bleyer v. Gross*, 120 N.W.2d 156, 160 (Wis. 1963); *see McGarrity v. Welch Plumbing Co.*, 312 N.W.2d 37, 44-45 (Wis. 1981) ("The court of appeals correctly held that an expert opinion expressed in terms of possibility or conjecture is insufficient[.]"). The Court will grant summary judgment on future medical costs for a lung resection.

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b. CT Scans.

The Court reaches a difference conclusion with respect to future CT scans. Dr. Hurst opines that the filter arms in Ms. Tinlin's lung "*will require* life-long follow up with CT imaging to document their stability." Doc. 15074-6 at 3 (emphasis added). He testified that he "think[s] she probably will need a CT [scan] either every year or every other year to just make sure that she's not developing an issue related to the fragments." Doc. 15701-7 at 3. This evidence is sufficient to support an award for the costs of future CT scans. *See Weber*, 681 N.W.2d at 143; *Pucci*, 187 N.W.2d at 142. The Court will deny summary judgment in this regard.

3. Chronic Cough and Asthma.

Defendants contend that Dr. Hurst could not determine whether Ms. Tinlin's chronic cough and exacerbation of her asthma are related to her filter. Doc. 15071 at 15 (citing Doc. 15073 ¶ 37). But Dr. Hurst found that the chronic cough "is almost certainly related to her tracheomalacia." Doc. 15704-7 at 3.[13] He further found that the tracheomalacia "would exacerbate asthma." *Id.* at 4. This evidence is sufficient to support a finding that Ms. Tinlin's chronic cough and asthma problems are related to her Recovery filter. The Court will deny summary judgment on this issue.[14]

IT IS ORDERED:

1. The following claims are **dismissed** based on Plaintiffs' withdrawal of the claims before Defendants moved for summary judgment: manufacturing defect (Counts I and V), failure to recall (Count VI), negligence per se (Count IX), and breach of warranty (Counts X and XI).

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[13] Ms. Tinlin's tracheomalacia presumably was caused by the tracheotomy procedure during her open heart surgery to remove a fractured strut from the right ventricle.

[14] Defendants assert in their reply that future medical costs are compensable only if they are "reasonably certain" to occur. Doc. 16011 at 10 (citing *Meracle v. Children's Serv. Soc'y of Wis.*, 437 N.W.2d 532, 535 (Wis. 1989)). But Defendants have not shown that this standard differs from the "probability" standard applied above. *See Meracle*, 437 N.W.2d at 535 (noting that *Bleyer* similarly held that medical testimony about future expenses must be expressed "not in terms of 'possibilities' but 'probabilities' ").

2. Defendants' motion for summary judgment (Doc. 15071) is **granted in part and denied in part** as follows:

a. The motion is **granted** on Plaintiffs' misrepresentation and deceptive trade practices claims (Counts VIII, XII, and XIV), and future costs for a lung resection.

b. The motion is **denied** on Plaintiffs' claims for failure to warn (Counts II and VII), design defect (Count III and IV), fraudulent concealment (Count XIII), and loss of consortium (Count XV), and future medical costs for CT scans, chronic cough, and asthma.

Dated this 16th day of April, 2019.

David G. Campbell
Senior United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC **ORDER**

The Plaintiffs Steering Committee ("PSC") moves to modify Case Management Order No. 6 ("CMO 6 ") to increase the common benefit assessments. Doc. 16932 at 3-6. Defendants and counsel for many individual plaintiffs oppose the proposed increases. Docs. 17367, 17387-17404, 17433, 17555. A hearing was held on May 29, 2019. Doc. 17966. For reasons stated below, the Court will grant the motion in part and deny it in part.

I. CMO 6 – Common Benefit Funds and Assessments.

CMO 6 was issued early in this MDL to provide for the fair and equitable sharing among plaintiffs and their counsel of the burden of litigating this complex case. Doc. 372 at 1. CMO 6 provides that compensable common benefit work includes meetings and conference calls, court appearances, discovery, document review, expert retention and development, legal research, motion practice, bellwether cases and trials, settlement efforts, and all other work that advances this litigation to conclusion. *Id.* at 1-2, 7-8. The time spent performing common benefit work must be authorized by Plaintiffs' Co-Lead Counsel and recorded accurately and contemporaneously. *Id.* at 8-9.

CMO 6 provides for the establishment of two interest-bearing accounts to receive and disburse common benefit funds: the "Bard IVC Filters Fee Fund" and the "Bard IVC Filters Expense Fund." *Id.* at 9. The Court has granted the PSC's request to establish these accounts and has appointed Citibank, N.A., as escrow agent. *See* Docs. 17777, 16932 at 2-3. The accounts will be funded through assessments on the gross monetary recoveries received by plaintiffs and their counsel in this MDL. *Id.* at 9. The current total assessment amount is 8%, which includes 6% for attorneys' fees and 2% for expenses. *Id.* at 10.

II. The PSC's Motion to Increase the Assessment Percentages.

The PSC proposes to increase the attorneys' fees assessment to 9% and the expense assessment to 5%. Doc. 16932 at 3. The PSC contends that the duration, scope, size, and cost of this litigation have outstripped the PSC's expectations when it proposed the initial assessment percentages. *Id.* The PSC further contends that the current percentages are conservative and MDL courts routinely approve increases as litigation develops. *Id.* at 4-5.

A. The Litigation's Duration and Scope.

Given that Bard had been litigating IVC filter cases for years when the MDL was formed in late 2015, the PSC asserts that "trials stretching into 2019 seemed unlikely." *Id.* at 4. The Court cannot conclude that bellwether trials were unforeseeable when CMO 6 was entered. Such trials are commonplace in mass tort MDLs and were discussed at the first case management conference. *See* Doc. 174 at 25-26.

The PSC estimated, however, that all bellwether trials would conclude by April 2017. *Id.* at 25. The final bellwether trial ultimately was scheduled for May 2019 – more than two years later than the PSC expected. Moreover, the parties did not complete all common discovery and file dispositive motions until late 2017, nearly a year longer than the PSC expected. *Id.* at 24-25. Although the overall duration of this litigation is not long for a mass tort MDL, the PSC's initial expectation that the litigation would end sooner was not unreasonable.

The common benefit work has included millions of pages of document review, substantial ESI discovery, dozens of depositions, many experts and Daubert challenges,

multiple summary judgment motions, numerous motions in limine, three three-week bellwether trials, post-trial motions and appeals, and substantial settlement efforts. Defendants' preemption motion involved more discovery and was more complex than the PSC anticipated. Several trial preservation depositions will yet be taken, and the PSC has agreed to prepare trial packets for lawyers whose cases are remanded or transferred.

The PSC states that while it was prepared for protracted litigation, it did not fully anticipate the scope of this MDL when it proposed the initial assessment percentages. Doc. 17687 at 3. The Court finds there was significant unanticipated common benefit work that justifies an increase in the attorneys' fees assessment percentage. The Court will increase the attorneys' fees assessment from 6% to 8%. The Court will not grant the requested increase to 9% because the Court does not agree with the PSC's argument that this case will include a significant amount of future work by the PSC. During oral argument, Mr. Lopez noted that some transferor courts may allow the parties to take updated depositions of Bard or other witnesses and that members of the PSC may be asked to consult with lawyers who try cases in transferor courts. Even if true, the Court does not view these as responsibilities of the PSC that should be charged to the common benefit.

The Court notes that the 8% assessment for attorneys' fees represents a holdback, not a determination of the final amount to be disbursed out of the common benefit fee fund. *See* Doc. 372 at 10.

B. Reliance on the Current Assessment Percentages.

In February 2019, the parties informed the Court that a large number of cases had settled in principle and many others were near settlement. *See* Doc. 15176, 15629. Nearly 2,000 of the cases settled in principle by execution of a settlement term sheet have been brought by the law firms of Freese & Goss and Matthews & Associates. Doc. 17367 at 1. Counsel from these settling law firms and Defendants have represented that another 2,000 or so cases are near settlement. The settling law firms argue that they relied on the 6% attorneys' fees assessment in negotiating the settlements, and that it would be unfair to increase the assessment at this late date. Docs. 17367 at 2-3, 17404 at 2. Other law firms

with cases in this MDL have joined these arguments. Docs. 17367, 17387-17403, 17433, 17555.

The purpose of a common benefit fund is to ensure that attorneys who perform work that benefits all plaintiffs and their counsel are reasonably compensated. The PSC managed and litigated this complex litigation to a conclusion, obtained a $3.6 million jury verdict in the Booker case and a fair settlement in the Tinlin case, withstood Defendants' preemption challenge to the viability of every plaintiffs' claims, and amassed evidence and experts that benefit all plaintiffs and their counsel. The settling law firms do not challenge the quality of this work, nor do they dispute that the work benefitted them and their clients significantly.

The justifiable reliance argument of the settling law firms has persuasive force, but the Court concludes that simple fairness requires that these firms – which will benefit financially from the work of the PSC – pay reasonable compensation to the lawyers who secured the benefit. The Court also notes that the PSC's motion is based in part on uncertainty about settlement values because Defendants and the settling law firms have declined to disclose the terms of their settlement agreements, even to the PSC. In light of this uncertainty, the PSC believes that the current 6% assessment for attorneys' fees may not be sufficient to reasonably compensate the PSC for the tens of thousands of hours of common benefit work performed to date. *Id.* at 3-4. This is a legitimate concern. The Court has no information about the value of the settlements reached to date, and concludes that this is another reason to increase the attorneys' fee assessment to 8%.

The Court reaches a difference conclusion with respect to costs. The justifiable reliance argument is more compelling when applied to individual plaintiffs. Although the PSC initially argued that an increased assessment would not change the amounts individual plaintiffs would receive in any settlement (Doc. 17687 at 2), it acknowledged at the hearing that costs generally are born by clients and the proposed 3% increase would be paid directly by individual plaintiffs, including those who have already agreed on settlement terms with Defendants. The Court is more concerned about increasing the amount of costs to be borne

by individual plaintiffs (especially after they have reached a settlement in principle) than it is about requiring lawyers to pay their fair share of the work that secured settlements for their cases. The Court will not increase cost amounts for individual plaintiffs at this late date.

IT IS ORDERED: The PSC's motion to modify CMO 6 (Doc. 16932 at 3-6) is **granted in part and denied in part**. The attorneys' fees assessment is increased from 6% to 8%. The 2% expense assessment is not changed. The first sentence of Section IV(B)(3) of CMO 6 is amended to read as follows: "The assessment amount is 10%, which includes 8% for attorneys' fees and 2% for expenses." *See* Doc. 372 at 10.

Dated this 31st day of May, 2019.

David G. Campbell
Senior United States District Judge